MARCH 14, 2018 P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 14, 2018 1:06 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 1 P.M.

(Pages 115 through 215)

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Proceedings Reported by Stenographic Court Reporter
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I N D E X

TESTIMONY

MISCELLANEOUS NOTATIONS

RECESSES

P R O C E E D I N G S

(Court was called to order by the courtroom deputy.)

(Proceedings begin at 1:06.)

(Jury not present.)

THE COURT: Thank you. Please be seated. 01:06:31

Counsel, we're missing one of the jurors. We're waiting for this juror to return. Hopefully, she'll be in in a moment so we're just going to wait.

While we're waiting, let me mention something else. Nancy will be filing this afternoon a proposed verdict form to 01:07:01 go along with the jury instructions, so please take those into account when you look at things over the weekend and be prepared to talk about those on the 22nd as well.

Any issues or questions before we start when the jury gets in here? 01:07:22

MR. O'CONNOR: Nothing from the plaintiff, Your Honor.

MR. NORTH: Nothing, Your Honor.

THE COURT: Okay. Hopefully the juror will be up soon. 01:07:29

(Jury enters at 1:11.)

THE COURT: Thank you. Please be seated. All right, ladies and gentlemen, as indicated, I'm going to give you some initial instructions and then we will turn to the opening statements of the parties. 01:12:04

You are now the jury in this case and it is my duty to instruct you on the law. It your duty to find the facts from all of the evidence in the case. To those facts you will apply the law as I give it to you. You must follow the law as I give it to you, whether you agree with it or not, and you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you. You will recall that you took an oath to do so. 01:12:07 01:12:24

At the end of the trial, I will give you final instructions. It is the final instructions that will govern your deliberations and your duties as jurors. 01:12:44

Please do not read into these instructions or the final instructions or anything I may say or do that I have an opinion regarding the evidence or what your verdict should be. 01:13:02

To help you follow the evidence, I will give you a brief summary of the positions of the parties. This is a personal injury case against a medical product manufacturer. The plaintiff, Sherry Booker, had a Bard G2 filter placed in her inferior vena cava, which we'll refer to throughout the trial as the IVC, the vein that carries blood back to the heart. An IVC filter is intended to catch a blood clot before they reach the heart or lungs. Defendants C.R. Bard, Inc., Bard Peripheral Vascular designed, manufactured and sold the G2 filter. 01:13:27 01:13:52

Ms. Booker alleges that the filter was defectively designed and that the defendants failed to warn about its risks. She alleges that she was injured by the filter and she seeks to recover money from defendants to compensate for her injuries and to punish defendants for their allegedly wrongful conduct. 01:13:56 01:14:11

Defendants deny that their filter was defectively designed or that they failed to warn of its risks. Defendants contend that the risks associated with the Bard IVC filter are understood by the medical community and are considered by doctors when deciding whether to use them. Defendants assert that they are not responsible for any injuries or damages suffered by Ms. Booker. There are two defendants in this case, C.R. Bard, Inc., and Bard Peripheral Vascular. From time to time the parties may refer to them as Bard or BPV. 01:14:30 01:14:52

You should decide the case as to each defendant separately. Unless otherwise stated, the instructions apply to all of the parties.

The evidence you are to consider in deciding what the facts are will consist of the sworn testimony of the witnesses, the exhibits that are admitted into evidence, any facts to which all of the lawyers have agreed, and those will be identified for you as agreed upon or stipulated facts, and any facts that I may instruct you to accept as proved. 01:15:10

In reaching your verdict, you may consider only the 01:15:33

testimony and exhibits received in evidence. Certain things are not evidence and you may not consider them in deciding what the facts are. I will list them for you. 01:15:37

First, arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they may say in their opening statements this afternoon, their closing arguments at the end of the trial, or at other times is intended to help you interpret the evidence but it is not evidence. 01:15:50

If the facts as you remember them differ from the way the lawyers have stated them, your memory of the facts controls. 01:16:08

Second, questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules and regulations of evidence. You should not be influenced by any lawyer's objection or by my ruling on it. 01:16:24

Third, testimony that is excluded or stricken or that I instruct you to disregard is not evidence and must not be considered. In addition, some evidence may be received only for a limited purpose. If I instruct to you consider certain evidence only for a limited purpose, you must do so and may not consider that evidence for any other purpose. 01:16:43

Finally, anything you may see or hear when the Court is not in session is not evidence. You are to decide the case 01:17:07

solely on the evidence that will be received during the trial. 01:17:10

Evidence may be direct or circumstantial. Direct evidence is direct proof of a fact such as testimony by a witness about what that witness personally saw or heard or did. Circumstantial evidence is proof of one or more facts from 01:17:35 which you can find another fact. You should consider both kinds of evidence. The law makes no distinction between the weight to be given to either direct or circumstantial evidence. It is for you to decide how much weight to give to any evidence. 01:17:51

There are Rules of Evidence that control what can be received into evidence during the trial. When a lawyer asks a question or offers an exhibit into evidence and a lawyer on the other side thinks that it is not permitted by the Rules of Evidence, that lawyer may object. 01:18:10

If I overrule the objection, the question may be answered or the exhibit received. If I sustain the objection, the question cannot be answered and the exhibit cannot be received. Whenever I sustain an objection to a question, you must ignore the question and must not guess at what the answer 01:18:30 might have been.

Sometimes, as I've already indicated, I may order that evidence be stricken from the record and that you disregard or ignore that evidence. That means that when you are deciding the case, you must not consider the stricken 01:18:46

evidence for any purpose. 01:18:49

In deciding the facts in this case, you may have to decide which testimony to believe and which testimony not to believe. You may believe everything a witness says or part of it or none of it. 01:19:05

In considering the testimony of any witness, you may take into account the opportunity and ability of the witness to see or hear or know the things testified to, the witness's memory, the witness's manner while testifying, the witness's interest in the outcome of the case if any, the witness's bias 01:19:24 or prejudice if any, whether other evidence contradicted the witness's testimony, the reasonableness of the witness's testimony in light of all of the evidence, and any other factors that bear on believability.

Sometimes a witness may say something that is not 01:19:45 consistent with something else he or she said. Sometimes different witnesses will give different versions of what happened. People often forget things and make mistakes in what they remember. Also, two people may see the same event but remember it differently. You may consider these differences 01:20:03 but do not decide the testimony is untrue just because it differs from other testimony.

However, if you decide that a witness has deliberately testified untruthfully about something important, you may choose not to believe anything that witness said. On 01:20:22

the other hand, if you think the witness testified untruthfully about some things but told the truth about others, you may accept the part you think is true and ignore the rest. The weight of the evidence as to a fact does not necessarily depend on the number of witnesses who testify about it. What is important is how believable the witnesses were and how much weight you think their testimony deserves. 01:20:25 01:20:41

I will now say a few words about your conduct as jurors. First, please keep an open mind throughout the trial and do not decide what the verdict should be until you and your fellow jurors have completed your deliberations at the end of the case. 01:21:02

Second, as I've already mentioned, because you must decide this case based only on the evidence received in the case and on my instructions as to the law that applies, you must not be exposed to any other information about the case or to the issues it involves during the course of your jury duty. Thus, until the end of the case or unless I instruct you otherwise, do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it. 01:21:18 01:21:39

This includes discussing the case in person, in writing, by phone or electronic means, via email, text messaging or any Internet chat room, blog, website or application including, but not limited to, Facebook, YouTube, 01:22:00

Twitter, Instagram, LinkedIn, Snapchat, or any other forms of social media. 01:22:06

This applies to communicating with your fellow jurors until I give you the case for deliberation, and it applies to communicating with everyone else, including your family members, your employer, the media or press, and the people involved in the trial although, obviously, you can notify your family and your employer that you have been seated as a juror in this case and how long you expect the trial to last. 01:22:20

But if you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and report the contact to the Court immediately. 01:22:39

Because you will receive all of the evidence and legal instruction you properly may consider to return a verdict during this trial, do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it. Do not do any research such as consulting dictionaries, searching the Internet or using other reference materials and do not make any investigation or in any other way try to learn about the case on your own. Do not visit or view any place discussed in this case and do not use Internet programs or other devices to search for or view anyplace discussed during the trial. 01:22:55 01:23:18

Also, do not do any research about the case, the law, 01:23:37

or the people involved including the parties, the witnesses, or the lawyers until you have been excused as jurors. 01:23:41

If you happen to read or hear anything touching on this case in the media, please turn away immediately and report the contact to me as soon as possible. 01:23:56

We have these rather detailed rules to protect each party's right to have this case decided only on the evidence that is presented here in court. Witnesses in court take an oath to tell the truth and the accuracy of their testimony is tested through the trial process. 01:24:15

If you do any research or investigation outside of the courtroom or gain any information through improper communication, then your verdict may be influenced by inaccurate, incomplete or misleading information that has not been tested by the trial process. At least it will be based on information that these parties never had an opportunity to address during the trial. Each of the parties is entitled to a fair trial by an impartial jury and if you decide the case based on information not presented in the Court, you will have denied the parties a fair trial. 01:24:33 01:24:52

Please remember that you have taken an oath to follow these rules and it is very important that you do so.

A juror who violates these restrictions jeopardizes the fairness of this trial and a mistrial could result that would require the entire trial process to start over again. If 01:25:08

any of you is exposed to any outside information, please notify me immediately. 01:25:13

I urge you to pay close attention to the trial testimony as it is given. When you deliberate at the end of the case, you will not have a transcript of what was said. 01:25:30

Even though we have a court reporter taking down everything that is said, it takes several days after a trial is over for the court reporter to go back and clean up that transcript and compare it with the recording and get it completely accurate. And that process won't be finished by the time you're deliberating so you will not have a transcript of the trial and as a result, we urge you to pay close attention to the evidence as it is given. 01:25:46

If you wish, you may take notes to help you remember the evidence. If you do take notes, please keep them to yourself until you go to the jury room to decide the case. Do not let note-taking distract you. When you leave each day or during a break, your notes should be left in the courtroom on your chair. Nobody will read your notes. Whether or not you take notes, you should rely on your own memory of the evidence. 01:26:01 01:26:21

Notes are only to assist your memory. You should not be overly influenced by your notes or those of other jurors.

From time to time during the trial it may become necessary for me to talk to the lawyers outside of your hearing, either by having a conference here at the side of the 01:26:41

bench as we did this morning or by calling a recess and excusing you from the courtroom. We will do our best to keep such conferences to a minimum. Please understand that the purpose of those conferences is not to keep relevant information from you, but to decide how certain evidence is to be treated under the Rules of Evidence and to avoid confusion and error. 01:26:46 01:27:00

I may not always grant a lawyer's request for a conference. Please do not consider my granting or denying a request for a conference as any indication of my opinion of what your verdict should be. 01:27:17

Trials proceed in the following way: First each side may make an opening statement. An opening statement is not evidence. It is simply an outline to help you understand what that party expects the evidence will show. The plaintiff will then present evidence and counsel for the defendant may cross-examine. Then the defendant may present evidence and counsel for the plaintiff may cross-examine. 01:27:37

After all of the evidence has been presented, I will give you instructions on the law that apply to this case and the attorneys will make their closing arguments. After that you will go to the jury room to deliberate on your verdict. 01:27:55

Counsel, are there any additions or corrections to the instructions?

MR. O'CONNOR: None from the plaintiff, Your Honor. 01:28:16

MR. NORTH: Nothing from the defendants, Your Honor. 01:28:18

THE COURT: Okay.

Ladies and gentlemen, before we have the opening statements, I am going to read to you some facts that the parties have agreed to. So these are what we call stipulated 01:28:26
facts and you should treat them as having been proven. They are basic background facts but it will save a little time in presenting evidence.

The defendants in this case are C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., referred to sometimes as BPV. 01:28:46
BPV is a wholly zoned subsidiary of C.R. Bard, Inc., the parent company. Throughout this case, including the opening statements the lawyers may make, we may refer to them collectively as "Bard" or "the defendants."

The product that is the subject of this lawsuit is 01:29:13
the Bard G2 IVC filter that was designed, manufactured, marketed and sold by the defendants. The G2 filter is conical in shape and consists of a main shaft to which 12 struts are attached. Six of the struts are arms and six are referred to as legs. G2 filter is constructed of a nickel-titanium alloy 01:29:41
called Nitinol. The G2 filter is a medical device that is implanted in the inferior vena cava, the largest vein in the human body. The United States Food and Drug Administration cleared the G2 filter for commercial availability through what is known as the 510(k) process outlined in the Food, Drug and 01:30:10

Cosmetic Act which is a federal statute. 01:30:16

The G2 filter was cleared for commercial availability in the United States for use in patients as a permanent device on August 29 of 2005. The G2 IVC filter was cleared for commercial availability in the United States for use in 01:30:39
patients as a permanent device with the option of percutaneous retrieval, meaning the ability to retrieve the filter, on June 15, 2008.

The plaintiff, Ms. Booker, was under the care of Dr. Dean Martin who recommended that Ms. Booker receive an IVC 01:31:06
filter. On June 21 of 2007, a vascular surgeon, Dr. Marcus D'Ayala, implanted a G2 filter in Ms. Booker's interior vena cava. On July 24, 2014, Dr. Brandon Kang, K-A-N-G, retrieved the main body of plaintiff's G2 filter percutaneously as well as one of the struts. He attempted but was unable to retrieve 01:31:42
a second strut located in her inferior vena cava or a strut located in the right ventricle of her heart.

On July 28 of 2014, the strut located in Ms. Booker's right ventricle was removed by Dr. Richard Harvey via open heart surgery. One strut remains in the wall of Ms. Booker's 01:32:07
inferior vena cava.

All right. Plaintiff's counsel, you may proceed with your opening statement.

MS. REED ZAIC: Thank you, Your Honor.

Good afternoon. Welcome. We went through a process 01:32:33

this morning with jury selection and you were selected and I have the pleasure of being the first attorney to address you after you formally have been impaneled and I want to thank you on behalf of my client, Sheri Booker, and our trial team for your service today. 01:32:51 01:33:04

The judge has just charged you with a certain set of preliminary rules, not necessarily rules of your own choosing but ones that you must follow and you'll be asked to follow throughout the course of this trial. You'll be asked to apply the law and the rules of society with regard to choices that people and companies make. 01:33:21

And when I say "choices," I mean deliberate choices that Bard, the defendant identified in this courtroom, made. And those choices resulted in consequences that harmed Ms. Sheri Booker. 01:33:36

The evidence we'll present throughout the trial primarily consists of documents internal at Bard. They are confidential documents that remained there and you will see for the first time. You'll also hear from witnesses that come in and testify live about some of those documents and sometimes they will appear by videotape. Of course evidence will also come from Sheri Booker herself with her background and her medical treatment. In the process of a jury trial, we get to tell Ms. Booker's story and I'm going to walk through an introduction of her story. I'm going to get into the chapters 01:33:55 01:34:14

of her story. 01:34:18

And part of the introduction is to orient you to Sheri, Ms. Booker. You met her earlier during the process of impaneling the jury. She's seated right here. Sheri.

I would like to tell you a little bit about her and 01:34:37
what brought her to her day in court. Sheri is a project coordinator at Home Depot in Georgia where she lives. She works in the Exterior Department and she helps coordinate and put together teams to evaluate projects and implement projects for siding and roofing and things like that. She's a mom. Two 01:34:53
boys, two grown boys, and she has hobbies and one of them is acting. That is a skill most recently that she provided on a voluntary basis which she does this weekend in a community play where proceeds are donated back to the community.

Sheri has suffered from health problems in the past. 01:35:18
They include cardiac problems but particularly of note here, in 2007 Sheri was diagnosed with cervical cancer and she needed surgery. And relevant to that surgery was the fact that she had also suffered from blood clots in the past. Blood clots, if they come loose, can travel up to the lungs and cause damage 01:35:40
to the lungs. Now, Bard's own witnesses and former employees will testify and tell you that there's no way to tell that if a clot does occur, that it will break off and it will travel and their products will protect you from that, protect Sheri from that phenomenon. 01:35:58

In fact, the testimony will show there's no way to show the percentage of clots that form that may ever travel outside the area of where the clot forms in the leg. But out of the concern for that history that she had of blood clots, it was decided by her doctors to implant her with an IVC filter. IVC, as the judge explained in sort of the preliminary fact or facts, which I'll go over and orient you with some visual aids as well as we go, because there's a lot of numbers and IVC stands for inferior vena cava. It's the largest vein in the human body that returns blood back to the heart. It's the highway to the heart and a filter, by nature of the sense of the word, filters and catches things. So an IVC filter is placed within this vein with the hopes it that will catch clots if they form and if they travel. 01:36:02 01:36:13 01:36:33

The IVC filter that Sheri received was a Bard filter. There are several companies, the evidence will show, that sell IVC filters but she received a Bard -- a filter made by Bard. 01:36:50

So in September of 2007 when she was diagnosed with cervical cancer and before her surgery, she was implanted with Bard's IVC filter called a G2, and this is important because Bard had more than one in its history of making filters. It was implanted in the largest vein in her body, again the IVC, and she was treated for cancer with chemotherapy and radiation and she survived and she went on with her life and the filter remained implanted in her. It was a permanent filter. 01:37:15 01:37:35

Over the next seven years, from 2007 until 2014, Sheri had gone back and forth to doctors and had hospital visits for various ailments over the time post her cancer surgery; but in 2014 she went to her doctor with pain in her abdomen and it was revealed to her that Bard's filter, that the evidence will show, should have remained in place, especially because of the area where this filter is implanted with blood flow to the heart was implanted in her and it broke into pieces. It tilted, it tore her vein and some of those fractured pieces went to the heart. 01:37:44 01:38:01 01:38:23

Sheri underwent two different procedures to remove the filter and the pieces that broke off. One was a percutaneous procedure to remove the filter where a piece of the fragment of the filter remains in her IVC today in her vein. She had two pieces that had gone to her heart and after that initial attempt to remove the filter in her vein. They also, during that first procedure, tried to remove the fractured pieces from her heart. And the doctor was unsuccessful. And it was not a clean surgery when it happened. 01:38:43

Going through the tricuspid valve, it was damaged during the process. She had to go in for a second open heart surgery, not just to remove the fractured pieces, but also to treat the fact that this fractured filter needed to be treated in the first place. 01:39:05

The evidence will show that Bard knew, based on the 01:39:21

design of the filter and the design of the filter that came before it upon which this design was predicated, or based on or compared, to use a few different synonyms, they knew that this filter put people like Sheri and did put Sheri at a higher risk of the these failures and these injuries. It was occurring at rates higher than its competitors. 01:39:24 01:39:42

As I said, there were other IVC filters on the market and the evidence will show that the laboratory testing that Bard conducted will show that Bard knew that the filter that Sheri was implanted with had a bad history of being able to resist pressures within that vein where blood was flowing through. 01:40:00

The evidence will also show that Bard did not conduct a long-term clinical trial on this device before it went into Sheri Booker. They conducted a pilot clinical trial that did not evaluate long-term safety and efficacy. It evaluated the ability to place the filter and to retrieve it. This was new technology. Filters, up until this point of this line of filters, were permanent and not normally retrieved. So the pilot study evaluating this IVC filter or -- the predecessor to this IVC filter upon which this design was based was only 12 weeks, had 35 patients, and was only to evaluate the placement and the retrieval. There was no long-term clinical study evaluating the seven years that it was in Sheri before it failed and no long-term study at that time looking at leaving 01:40:18 01:40:38 01:41:00

there permanently, which it was intended to be for Sheri. 01:41:03

Ultimately, the evidence will show that Sheri's doctor stopped using IVC filters, not because Bard told her about these issues of fracturing and migration and tilting and the things that happened in Sheri, but he began reading and 01:41:22 seeing how this filter was performing in the public through reports and medical literature and that's why he stopped using it after he had placed this in Sheri. The reports the medical literature, the evidence will show, are not complete in the sense that not every time an adverse event happens, it is not 01:41:42 immediately reported to a manufacturer or the FDA, if ever. Not every event is reported.

All medical devices carry risks when placed in the body. And when a device company knows that its device increases those risks, harm occurs. And it did. 01:42:00

Now, I have been talking about these filters sort of in the abstract and what I'm showing you right now is a picture of three different filters manufactured by Bard. To your right, all the way on the right-hand side, is the G2 filter that was implanted in Sheri Booker but that's not the beginning 01:42:26 of the story of the IVC filters. All the way on the left is a filter that Bard acquired the technology for. It was a permanent filter called the Simon Nitinol filter. Sometimes you'll hear witnesses referred to it as Simon or SNF. That was a permanent filter. 01:42:49

And the start of Bard's poor choices is when it had this permanent filter, which worked and the evidence will show had a good safety profile, it intended to redesign it so that they could make the filter in the middle called a Recovery that was a permanent filter but designed to also have the option to go in and retrieve it. In other words, the Recovery filter. You could go in and recover it from the body. 01:42:50 01:43:15

The evidence will show that the negative clinical experience that Bard had with that filter in the middle, which they based the design of Sheri's filter on, should have informed them, and it did not that it would put patients at higher risks of these injuries. 01:43:31

Let's look at them one by one. The Simon Nitinol filter, the permanent filter. It was technology acquired from a company called NMT. It was a permanent filter. And when Bard acquired this technology, the development of the Recovery filter, that first retrievable filter, was already developed. When they acquired this, they also acquired the engineer that was within the same time period that was working on these particular filters. 01:43:49 01:44:07

And the evidence will show that the SNF, or the Simon filter, was a permanent filter with an impressive safety record acknowledged by Bard's own witnesses, employees and former employees, including their former medical director.

You'll hear from Mr. Carr himself, an engineer. 01:44:25

He'll come and testify live in this trial that Bard wanted to enter into a new area of technology, so this first permanent filter that was performing well, again, was not retrievable. And Bard wanted doctors and the medical community wanted, the evidence will show, a retrievable filter. 01:44:27 01:44:44

Looking at the Simon Nitinol filter on the bottom now, when they redesigned it and made the Recovery, Rob Carr was involved and the Recovery was in the works when they acquired this technology. And in order to get it approved -- excuse me. In order to get it cleared for market, they had to show that it was substantially equivalent to the Simon Nitinol filter. 01:45:13

Now, let's talk about that term for a moment, substantially equivalent. These filters are not FDA approved. They are FDA cleared. In order to get approval from the FDA, it is a very rigorous process. Bard did not go through that process. Bard went through the clearance process where, instead of having to show independently that a device is safe and effective, they went through a comparative process where they had to show that they are as good as another filter on the market. They are substantially equivalent to another filter. 01:45:29 01:45:49

And that is how and that is why I lined these filters up for you, starting with the Simon Nitinol filter. There was a clearance for the Recovery filter that was shown to be substantially equivalent to the Simon Nitinol and then the G2 01:46:07

filter that Ms. Booker received, also known as the Recovery G2, because it was another version of the Recovery filter also known as the modified Recovery filter. They build on each other like building blocks. 01:46:10

Bard chose to use these devices and show substantial equivalence. It was in control of that choice and it chose the products that it had to show substantial equivalence to. It chose its own products. So going from the Simon Nitinol filter, which was the permanent filter, the developments of the Recovery filter was a new era for Bard. And testimony in this case will show that in order to develop a new medical device product, you need to understand the environment in which it is being used. 01:46:25 01:46:46

You'll hear from an engineer who will probably testify this week. In fact, experts are hired on both sides of this matter. Not surprisingly, they don't always agree. You'll hear from an engineer that the very first step of designing a medical device to put in the human body is to understand where it goes, to understand the environment of use. 01:47:04

If you would look at your screens, I would like to take you a little more up close and personal to the inferior vena cava and the environment in which these filters are placed. There are the lungs surrounding the heart and the vena cava is the large blue vein returning blood. And if you look at the proximity of the vena cava, which is the blue vein -- on 01:47:25 01:48:01

the right is the red. That's the aorta. And you can see how close these filters are placed and the proximity to the organs and the aorta. 01:48:07

As I said, it's the highway to the heart and the evidence will show this is an area where blood flows through and the environment and understanding the environment of knowing that whatever hits that filter or the filter itself is headed towards the heart, understanding the environment of use. 01:48:20

Bard knew an IVC filter could expand and contract. Bard knew that the IVC filter could expand and contract up to 50 percent of its size, but its testing didn't look at that. It didn't examine the environment of use and how that vein would expand and contract. They tested these filters in simulated vena cavas as wide as 28 millimeters -- thinking of millimeters like the ticks on a thermometer -- prior to putting a Recovery on the market. It never tested for the dynamic changes occurring in the vena cava that you've seen in this representation or the changes in the size of the vena cava with simple movements or activities like sneezing and coughing and other common events. 01:49:03 01:49:22 01:49:38

And the reason you test, the testimony will show, the reason you test is that you can understand what can happen before you market a product that is to be placed in humans and sold widely. And the expert testimony you'll hear will explain that it's not just Bard's filters that had a higher instance of 01:50:01

migration, tilt, fracture, and perforation, all of which Ms. Booker suffered. It's also the fact that there's a cascade of complications when three happen together like they happened in Ms. Booker. And you'll be able to evaluate the evidence that Bard did not warn adequately about the interaction of these events and how one can lead to the next with harmful effects. 01:50:05 01:50:27

Let's look at each one individually. This is a still shot of the video that you've just seen with the filter placed in the vena cava. And when a filter tilts, it loses its centering. And the testimony will show when these are placed, they need to stay centered, and they need not to move. They can become embedded in the vena cava wall when they tip. It can change the blood flow and it can lead to fractures, migration, perforation, clot creation, and something called caval thrombosis. 01:50:46 01:51:06

Migration, there are two different kinds, one called cephalad, which is a fancy word for towards the heart, and one for caudal, which is a downward movement. So the filter can migrate north, so to speak, up towards the heart, or downward towards the feet. Ms. Booker suffered from a caudal migration but she also suffered from tilt migration, fracture, and perforation. As I've said, the evidence will show that a tilt can lead to those future failures. 01:51:23

I have another animation to show you that Greg will help with. 01:51:47

So this animation actually shows a tilt and a fracture with the filter tipping embedding in the side of the caval wall. The evidence will show when this happens, there can be a lack of efficacy and the pressure on the components can lead to a fracture. Again, largest vein in the body returning blood to the heart. Sheri suffered a fracture and, as I explained, it traveled to her heart. 01:51:48 01:52:14

Sheri also suffered from a perforation. This depicts the filter tilting, embedding, and perforating through the side of the vena cava wall. 01:53:43

And as I pointed out earlier, right next to the vena cava is the aorta which also appeared -- Sheri Booker's aorta, and this is actually an overlay of Sheri's x-ray showing the tip, the tilt and the perforation to her aorta.

The evidence will show that when it comes to these problems, Bard conducted bench testing starting with its first retrievable filter, the Recovery filter. And when I refer to bench testing, a bench is simply a piece of furniture in the lab where the equipment sits and laboratory testing, you'll hear throughout the trial through testimony and documents. 01:54:18 01:54:38

Bard conducted bench testing. It conducted bench testing for migration resistance and that means that it tested the ability of a filter to resist the migration of the blood flow and the forces in the environment where that filter is placed. And to do that, they used PVC piping and sausage casing. 01:54:57

The evidence will show that Bard also conducted tests on sheep, migration resistance testing, and saw higher levels than were actually being reported from the bench in clinical trials. 01:55:03

Bard also, as I mentioned, did an initial clinical study, a pilot study, of 35 patients to test retrievability. Rob Carr, the engineer that came with the technology from NMT to Bard, hired Dr. Murray Asch who you will see in court potentially this week testifying about this initial pilot study. 01:55:19 01:55:42

When Dr. Asch conducted his clinical trial for retrievability, it consisted of 35 patients and the results of that study included 22 procedural difficulties; five tilts, for which no root cause analysis was conducted by Bard; one perforation; one caudal migration, meaning downward; one cephalad migration, upwards; arm fractures, meaning the tops of the filter that you saw; and leg fractures, meaning the bottom of the filter. 01:56:13

After the fractured leg hook that you see at the bottom of the slide, the study was suspended to investigate what happened. After the investigation was concluded, the study continued. Dr. Asch advised, and his testimony will prove, that he advised Bard that although implantation and retrievability was successful in his 35-patient study, there were multiple failure modalities requiring a long-term clinical 01:56:36 01:57:00

trial to determine safety and efficacy and that Recovery was not ready for market. 01:57:04

Coincidentally, the testimony and evidence will also show that when Bard acquired this technology from the company that it bought it from, at that time that company had a long-term clinical trial planned to occur in Europe which never took place and not before Sheri Booker received her filter. 01:57:17

So let's talk about Bard's choices. Considering all of that, why did they market it? And the testimony and evidence in this trial will show that they had an opportunity. 01:57:45 They had the opportunity to be first to market with the first retrievable IVC filter in the form of the Recovery filter. That middle filter I showed you on the first slide. The first product on the market holds the market share.

And recall these are not FDA approved. These are FDA cleared. 01:58:11 And you'll hear during the trial that the FDA clearance process is an exemption to the approval process. You'll also hear it referred to as the 510(k) process as His Honor mentioned to you in the facts stipulated to at the beginning of the trial. 01:58:35

The 510(k) clearance process, the number 510(k) is the code section. It's a regulatory number showing the code in the regulations. An analogy would be those that have access to 401(k)s, that is a tax code section. 510(k) is a regulatory code section. 01:58:54

So 510(k) is the regulation that allows medical devices to be cleared to market, not approved, based on a comparison to another device on the market, like I said earlier; and Bard chose this path of clearance, not approval, by comparing its products to its own products in order to get them cleared. It's an honor system. FDA does not test. FDA does not have hospitals to test in. FDA does not verify the data that the manufacturer provides. 01:58:56 01:59:10

Expert testimony in this case will tell you that you must -- a manufacturer must assure the FDA that any device submitted under this 510(k) route, because it's an exception, is comparatively as safe and effective. It has to be compared to another device, not independent safety and efficacy, but a comparison is it as safe and effective. 01:59:34

When Bard submitted its 510(k) submissions for its retrievable filter and the G2 after it, there was a quote. They had to assure the FDA that the data and information submitted in the premarket notification are truthful and accurate and that no facts material for review of the substantial equivalence of this device have been knowingly omitted from this submission. And that's because it's an honor system. Again, the FDA does not test. 02:00:07 02:00:25

So let's go back through the regulatory history before we move on. The Bard had a permanent filter, the Simon Nitinol. It wanted to enter the retrievable IVC filter market. 02:00:52

They went through the 510(k) process and showed the FDA that 02:00:57
the Recovery filter was substantially equivalent to its
permanent Simon Nitinol filter. After that, after reports of
adverse events, they redesigned the Recovery filter with a new
Recovery filter also called the G2. 02:01:16

The G2 was initially cleared with the FDA as a
permanent device, as was the Recovery, and later given the
ability by the FDA to retrieve it. But the claim here is it
was substantially equivalent initially to the SNF.

I think the evidence will show that it was not. The 02:01:36
depiction I have up on the screen right now is the information
that Bard had internal about its testing. It tested the
migration resistance, again, the ability for a filter in this
environment to resist migrating out of place, to resist
movement, and they had data that the Simon Nitinol filter could 02:01:56
resist migration at 80 millimeters of mercury. That's a
pressure measurement. 80. Their data showed that the Recovery
filter could only resist migration at 50.

The standard that they set internally was their own.
What they reported to the FDA is that it was substantially 02:02:18
equivalent with setting a standard of 50 millimeters of
mercury, knowing that what they were comparing it to could
resist as high as 80. That means the Recovery filter could
move more easily. And the evidence will show that Bard knew
that but they did not provide the raw data to the FDA. Their 02:02:37

bench testing showed it. Their sheep study showed it. And eventually when they did a clinical trial, the pilot study, just for retrievability, there were incidents of migration fracture, and perforation in that study. Bard's own employees will testify to that as well as Dr. Asch. 02:02:41 02:02:56

Again, 510(k) clearance process is an honor system. There's no testing that the FDA does themselves on medical devices, specifically on field devices. Let me make that clarification. And the FDA relies on accurate data provided by manufacturers. Bard made the claim of a 50 millimeter of mercury standard knowing that comparing it to the permanent filter, that was inaccurate. Bard chose to keep the important information to themselves. Not only did they not share it with the FDA, they didn't share it with their sales staff. And the evidence and testimony will show that sales staff in a hospital and doctor's office is a primary mode of communication between the company and the physician. It was not shared with the medical profession and it was not shared with the end users of the filter. 02:03:16 02:03:42

Now, you've seen Bard's choices and the evidence will show the truth which is that in 2008, a year after Sheri Booker received her filter internally, Bard was getting together and looking back at their device regulatory history with the mounting adverse events that were being reported. If they decided that they were device focused, they had a lack of 02:04:02 02:04:23

thorough understanding of dynamics of caval anatomy, meaning the anatomy of the vein, the IVC, and that impacted their testing methods. They had a limited understanding of user needs and that they have a historical reactive evolution design mind set. Recall that they first produced the Recovery filter, then they redesigned it as adverse events were coming in. Product complications force the focus onto reactive designing. 02:04:27 02:04:46

This was their choice. Bard chose to do this. They canceled the plans for the long-term study in Europe by the predecessor company that owned the original technology. They relied on data from the public rather than doing a long-term clinical trial themselves. Data being reported in from the public, the voluntary reporting system that doctors have in this country of reporting to the manufacturer, they were looking at that in order to redesign their products. They ignored the cause of obvious Recovery failures prior to designing the G2 and those failures were migration, fracture, tilt, and perforation, all of the failure modalities that Ms. Booker suffered. 02:05:10 02:05:25

Bard knew that the Recovery was not safe for market and they had not solved their obvious problems. And knowing that, they chose to continue to ignore filter failures. Recovery was cleared for market based on the FDA honor system and Bard had never tested the environment of use. 02:05:45

And how did they handle that? How did they do it? 02:06:08

The evidence will show it was marketing. Their own internal documents will reveal, and testimony will reveal, that the message they were sending out to the medical community was how does Bard deal with untested failure modes? And the answer was: Users can be swayed by aggressive marketing in spite of negative clinical experience. 02:06:11 02:06:23

Bard continued to ignore and not solve the multiple failures that were coming in and kept their products on the market and the consequences are tilt, migration, perforation, and fracture, all of which Sheri Booker suffered. 02:06:50

To look at specific consequences, the Recovery filter, which was the predecessor to the G2, went on the market for full market release in 2003. By December of that year they had adverse events of migration, caudal and cephalad, downward and to the heart, and fracture. 02:07:11

And within the same month they were putting together a product design team to look at -- to question the design of the Recovery filter. Related to the issue of migration, the review team would like to see objective elements of the following elements: Documentation that explains the establishment of the 50 millimeters of mercury acceptance criteria for migration resistance. The evidence will show that as early as 2003 this line of filters internally, without sharing, they were questioning the design. 02:07:30

Two months later, the Recovery filter experienced its 02:07:50

first death in the field. There was a migration death reported with the filter migrating to the heart, February of 2004. 02:07:52

During the Asch study, after the investigation of the fracture that I mentioned that stopped the study, the standard was that if another major migration were to occur, they would stop the study and reevaluate the entire filter design. But once it was on the market, four years later, in February of 2014, after the first migration death of the same filter that had been tested in Dr. Asch's hospital, they changed the standard. If a migration requires surgical intervention during the course of this investigation, the Recovery filter will be placed on hold, not redesigned, on hold. 02:08:09 02:08:30

Two months later the Recovery filter experienced a second death in the field, a migration of the filter to the heart and Bard put it on hold. But the evidence will show they didn't tell anybody. They put it on hold internally and continued to sell the product. 02:08:49

The next day, instead of making an announcement that the product was on hold, the evidence will show that Bard hired a PR firm. They created a crisis communication plan as the word got out that people were dying from this filter; and their consulting physician, the evidence will show, stated that on migration resistance testing, I wouldn't raise this subject if at all possible. 02:09:25

A few days later Bard engaged in a Remedial Action 02:09:47

Plan and the same physician who said we shouldn't mention migration filter resistance said that there were no design or manufacturing defects found to be associated with the filter. 02:09:49

And not long after that, within days, the hold was lifted and Bard continued to sell. But two days after that, the evidence will show that Bard was already in a meeting trying to redesign the Recovery filter, redesign to the G2, the next generation of Recovery filter that went into Ms. Booker. They realized at that time that this 80 millimeters of mercury pressure versus 50 millimeters of mercury pressure was a problem and that G2 had to match, it had to be substantially equivalent to the Simon Nitinol filter which could resist a higher pressure in that vein as shown to them in their simulated bench testing. 02:10:07 02:10:33

Additionally, about a month after their consulting physician, who said don't mention migration testing, the evidence will show that a quality engineer named Natalie Wong, who will testify via videotape in this trial, had looked at the same data and found that there was a statistically significant difference between the Recovery and its predecessor device, the Simon Nitinol. 02:10:50 02:11:09

By July of 2004 Bard is still questioning their design. Why migration deaths did not lead to a product hold. The message was the Recovery filter has been tested to verify that it meets the migration resistance parameters that have 02:11:32

been used for the Simon Nitinol filter. 02:11:35

Similar to the way they had gotten around their issues prior to that with the Recovery filter, the evidence will show, they turned to marketing.

The same physician consultant that said don't discuss 02:11:48 migration resistance, he did a comparative test, comparative meaning looking at Bard devices with its competitors, and the reports of death were 4.6 times higher than all other filters. Filter migrations were 4.4 times higher. And filter perforation was 4.1 times higher. Filter fracture was 5.3 02:12:11 times higher and these differences were statistically significant.

During the process of moving from what they called a crisis for which they developed a communication plan, Bard was in the midst of redesigning to create the Recovery G2 filter. 02:12:33 And one of their caudal migration tests, which is a bench test, a laboratory test showed that the G2 could not perform as well as the Simon Nitinol. And using the Simon Nitinol as a predecessor predicate filter to compare like the Recovery filter had done, like they had done with the Recovery filter, 02:12:57 it failed.

In looking at the bottom of the graph, it may be difficult to see but the line with the triangles is the G2 and its performance. And when comparing to it their first permanent filter, the one that the medical director, the 02:13:10

evidence will show, said had a good safety profile, so you can see at the top the SNF and the pink squares was performing better. 02:13:14

So in order to get clearance of the G2 device, the evidence will show that Bard packaged this up for another 510(k) application and instead of comparing it to the Simon Nitinol filter, they changed it and made the predicate the Recovery device. 02:13:32

If you recall, those three filters that I showed you, Simon Nitinol, Recovery, G2, the building blocks, the Recovery did not perform as well as the Simon Nitinol and as it was failing, the redesign showed that the G2 could not perform as well so it compared it to the Recovery filter and it was cleared. 02:13:48

And as I mentioned before, the evidence of Bard employees saying that marketing could solve the issues that they were having, this is the G2 brochure, the marketing brochure that Bard created for its new G2 filter, the one that went in Sheri Booker. It says: We're taking strength and stability to a new level. 02:14:18 02:14:36

And the testimony in this case will show that it did take to it a new level, a lower level.

It also represented that the G2 increased migration resistance and improved centering and enhanced fracture resistance. That was in August of 2005. By December of 2004 02:14:51

the acting medical director at Bard, after looking at the reports of injuries coming in associated with the G2 filter, which was the modified Recovery, said I would like to look more generally at the G2 complaints. I have seen problems with caudal migration, tilting, perforation, mis-deployment and maybe one or two additional things. 02:15:01 02:15:15

The medical director also went on, the evidence and testimony will show, to question the consequences of these migrations and it concerned him with regard to efficacy of these filters, not only the safety but the efficacy. The same medical director went on to say, the evidence will show, the G2, which is implanted in Ms. Booker, is a permanent filter. We also have the SNF. That has virtually no complaints associated with it. Why shouldn't doctors be using that one rather than the G2? 02:15:35 02:15:57

And the evidence will show this was not shared. This belief, this comment by the medical director at Bard, was not shared with the medical community and it was not shared with the FDA. In 2006 a product design testing protocol was run. And you can see on the graphs on your screen on the right-hand side where it's blown up, caudal migrations for the G2 filter, all the way to the left, were higher than both the Recovery and the Simon Nitinol filter. 02:16:19

Bard continued to trend its products and you can see on the screen that you're looking at now the evidence will show 02:16:42

that when comparing the Recovery filter with the G2, caudal migrations with the G2 were higher, tilt was higher, and perforation was higher. 02:16:45

In March of 2006, Natalie Wong who, again, you will hear testify via videotape, began do investigate and determined that the number of G2 caudal migrations, the downward migrations which Sheri Booker suffered, represented an unacceptable risk due to their failure mode effects analysis that they looked at. That means that caudal migration was determined to be an unacceptable risk, a failure that contributes to death, severely injury, permanent significant disability or severe occupational illness. 02:17:04 02:17:27

Now, Bard did conduct another clinical trial, not before the G2 was marketed, at the time it was marketed, and at the time it was inserted in Sheri Booker, there still was the single pilot clinical trial study performed by Murray Asch with the 35 patients to look at retrievability. 02:17:43

But after it went on the market, Bard began to recruit for another clinical trial called the EVEREST study and the intent, again, was to look at retrievability. It was not a long-term safety and efficacy study. It did not look at the long-term effects. It looked at retrievability and the purpose of doing that test is that when it hit the market, the G2 was cleared only for permanent placement. And, again, this option, the opportunity of having a retrievable filter, was valuable. 02:18:02 02:18:21

The slide in front of you, I apologize, is small but it presents the filter complications that were shown in the EVEREST trial. Caudal migrations were high, fractures, tilts, penetrations. The evidence will show that there were 83 people in this test. 100 were enrolled. Only 83 completed the protocol and the test and, as you can see, the evidence will show the incidence of caudal migration, tilts, and penetrations were high. 02:18:29 02:18:45

Again, back to the cascade of failures Sheri Booker suffered: Tilt, migration, perforation, and fracture. The evidence will show that Bard was seeing this at higher rates. In the Recovery filter, the predecessor prior to Sheri Booker receiving her G2, and then afterwards with the reactive mind set that they had. 02:19:14

She suffered individual caudal migration. Her filter tilted 18 to 20 percent according to the evidence. She had six perforations: An eight millimeter penetration into her any aorta, which you saw the depiction of on the screen; penetration into her spine; and perforation of the psoas muscle, which is the muscle in the lower abdomen. She suffered three fractures: One surgically removed, one removed through open heart surgery in the right atrium, and, as I said, one piece remains in her vena cava today. 02:19:35 02:19:56

Sheri Booker endured two removal procedures for a filter that was supposed to be permanent seven years after she 02:20:22

received it with no clinical trial showing long-term safety and efficacy. 02:20:24

This is her first surgery percutaneously with an attempt to remove the filter pieces from her heart and the filter from her vena cava. 02:20:45

This is an x-ray of her filter and a depiction of the procedure she endured. Her doctor was unsuccessful at the first attempt to remove it and the second time he used a different tool. He was able to collect the filter but the filter fragments remained behind. 02:22:30

And this depicts the successful removal of one of the pieces that was perforating her aorta and a piece still remains in her vena cava. This is a depiction of the surgery I described to you earlier with the filter fragment that had traveled to her heart and Dr. Kang's attempted retrieval which was not a clean surgery in attempting to remove it. 02:23:30

And the evidence and testimony that you'll hear in this trial is when Dr. Kang was attempting to remove this filter, as I said, it was not a clean surgery. His attempts to remove it, there was damage to some of the structures in her heart while attempting to remove the filter that had migrated to her heart. And with one piece still remaining in her heart at that time and the damage due to the attempts to retrieve the filter fracture, a piece in the first place, Sheri then underwent open heart surgery. 02:24:43 02:25:39

During this surgery you'll hear testimony about it that Sheri was put on the heart-lung machine to bypass during this procedure. 02:28:49

The fracture is still embedded, seen at the bottom of the screen. And this scan is a cross-section looking from the bottom of the body up. Whereas the first attempt of the percutaneous matter was unsuccessful, the open heart procedure was successful to remove the fragment from Sheri's heart and the damage and the difficult surgery of attempting to retrieve it the first time was repaired. 02:30:36 02:32:08

The evidence will show that Sheri suffered a lot and along with those risks that she endured without knowing it leads to future complications. And the testimony in this case and evidence will show that she is at a future risk of deterioration of the tricuspid valve potentially requiring valve repair in the future. She has a 60 percent mortality rate survival right at ten years and there is an irretrievable filter fragment as of now in her vena cava putting her at future risk for embolization of that fragment to her heart as it still remains in the vena cava which returns blood back to the heart. 02:32:46 02:33:07

I've talked you through an introduction and the chapters of Sheri's story, of Bard's choices, and the next chapter is up to you. Your role as jurors, you'll be evaluating evidence as the judge has charged you. You'll be 02:33:28

making the decisions based on what you see and deciding the outcome at this point. 02:33:33

All medical devices implanted in the body carry risks. And when a company knows its new medical device increases the risks but sells it anyhow, harm occurs. And all IVC filters carry risk. 02:33:49

But Bard knew its IVC filters increased the risks but sold them anyway, and Sheri Booker suffered permanent injuries, risks of deterioration of her tricuspid valve due to the attempts to repair the damage that was done by the fractured piece that went to her heart and may have future surgeries. 02:34:10

Again, I thank you for your service.

THE COURT: All right. Thank you. Members of the jury, we will take an afternoon break at this point. We will plan to resume at ten minutes to the hour. Please remember not to discuss the case and we will excuse you at this time. 02:34:32

You can go ahead and go right out the door.

(Jury departs at 2:34.)

THE COURT: All right. We will see you at ten minutes to the hour. Thank you. 02:35:10

(Recess at 2:35; resumed at 2:51.)

(Jury enters at 2:51.)

(Court was called to order by the courtroom deputy.)

THE COURT: Thank you. Please be seated.

Mr. North, you may proceed. 02:52:50

MR. NORTH: Thank you, Your Honor. 02:52:54

May it please the Court, ladies and gentlemen of the jury, good afternoon. As I introduced myself at the beginning of the case, my name is Richard North. And by coincidence, I come from Atlanta, Georgia -- if you hear a little twang in the accent -- the same place that Ms. Booker lives. And my partner, Elizabeth Helm, also resides in Atlanta with me. And we are joined with Mr. Jim Condo who practices law here in Phoenix. 02:53:05

For the rest of the my presentation today, I would like to tell you what we think the evidence will show which is the other side of the story here. The evidence you will hear during this trial goes far beyond the bits and pieces we believe that you were just presented with. The evidence in this trial over the next three weeks will go far beyond the selected documents that may be taken out of the context that you've seen. 02:53:26 02:53:46

And the evidence will also go far beyond the snippets of testimony you've heard. And taken in context, we believe that the whole story, all of the evidence, will demonstrate to you that the G2 filter, the filter at issue in this case, is a life-saving device and that because of that and because of that whole story, that Bard stands wrongly accused in this courtroom. 02:54:01

The key issue throughout this case through the 02:54:21

testimony, through the witnesses, through the documents and even ending I believe in the judge's charge about or instructions to you about the law is going to be the risk-benefit analysis, whether the risks associated with this G2 filter outweigh its benefits. 02:54:24 02:54:40

Now, for the last hour plus you have heard a lot of evidence about the so-called risks associated with inferior vena cava filters. You did not hear much about the benefits. And let's talk for a moment at the outset what the evidence will demonstrate concerning the benefits of this device in a patient like Ms. Booker. 02:55:04

Ms. Booker, unfortunately, has had a complicated medical history. She had two heart attacks by the age of 32. At the age of 32 she had her first pulmonary embolism, something that you will hear during the course of this case, could have easily killed her. Five years later, in 2007, she had a second pulmonary embolism also involved with deep vein thrombosis, or clotting, in the legs before it went up to the lungs. 02:55:27

Only a few months -- and once she had that second pulmonary embolism, her doctors tried to prevent another one from occurring. And knowing that another pulmonary embolism could kill her, put her on anticoagulants, which we know of often, those of us not in the medical field, often refer to as blood thinners, things like Coumadin. They put her on a blood 02:55:47 02:56:10

thinner trying to prevent a third clotting episode which could be fatal. 02:56:12

But then several months later she was, unfortunately, diagnosed with cervical cancer and she had to have a surgical procedure done to treat that cancer and her doctors were in a quandary. What are they going to do? She cannot be on these blood thinners and anticoagulants and undergo a surgical procedure. She might bleed to death. What could they do to protect her about the possibility of a third pulmonary embolism which could have killed her also? 02:56:26 02:56:52

What they did was they implanted a Bard G2 filter in 2007 and that filter remained in Ms. Booker for seven years and not once in that seven years did she ever have another pulmonary embolism.

I submit to you, ladies and gentlemen, that's the best evidence of the benefits and the life-saving benefits of this device. 02:57:15

As I mentioned to you, my purpose today is to try to present to you what we believe the whole story is not just an occasional chapter, missing other chapters, not an occasional page, missing other pages, but to summarize for you the whole story. And we are going to ask you to please keep an open mind during all of this case until you have heard all of the evidence and the whole story. And we believe that when you hear the whole story, and not the bits and pieces that you 02:57:34 02:57:56

heard earlier, it's going to tell you a different story. 02:57:59

Some chapters were missing today, chapters such as the notion that they claim evidence that Bard's marketing expenditures exceeded their research and development investment. There will be no evidence of that. They seem to 02:58:16 suggest Bard's testing was flawed, but the whole story will show you that the testing was comprehensive and that the testing was not just rubber-stamped but was reviewed in detail by the United States Food and Drug Administration. And we ask you to keep an open mind until you have heard, by the 02:58:38 conclusion of this case, the whole story.

The purpose of opening statement is to provide you a roadmap, a sense of where we're going, I plan to go along the way, and I would like to talk to you today and give you the roadmap. Four stops along the way. 02:58:58

First I wanted to talk to you about the defendants. I want you to know who my clients are. Then I want to talk to you more about the device, G2 filter, then I would like to talk to you a little bit more about Ms. Booker's medical history and then I would like to talk to you about the plaintiff's burden, 02:59:20 the elements they have to show to recover in this case and what the evidence says regarding each of those elements.

Let's begin with the defendants, Bard, C.R. Bard, and Bard Peripheral Vascular and I have the honor to represent the men and women of those two companies. 02:59:42

Bard was found more than 100 years ago by a physician by the name of Charles Russell Bard who became interested in treating urinary discomfort and developed what was called the -- or still is called today the Foley catheter, a device I'm sure many of you have been exposed to in the hospital setting. The company has been around for over 100 years. The company is located in Murray Hill, New Jersey, and it has a number of specialty areas: Vascular, urology -- that's how I first got involved with Bard, they have a Urology Division outside of Atlanta -- oncology, surgical specialty. 02:59:47 03:00:04 03:00:28

And then here in Tempe, Arizona, is the Vascular Division, Bard Peripheral Vascular. And during the course of is trial, you're going to meet a lot of the men and women from Bard Peripheral Vascular.

This company develops vascular and oncology devices. It's one of the leading seller in the country of biopsy needles for the treatment of breast cancer. It sells stents, drug-eluding stents for the treatment of coronary artery disease. It sells filters. It sells ports. It sells a lot of medical devices used to treat very serious conditions but Bard is not a nameless, faceless corporation. It's made up of men and women professionals, many of whom you'll meet. It's made up of engineers, one who will be I think the first witness, Andre Chanduszko. It's made up of physicians. It's made up of regulatory specialists. It's made up of clinical study 03:00:48 03:01:09 03:01:34

analysts and quality assurance specialists, men and women seeking to follow core values to introduce innovative medical products for the treatment of serious illnesses and conditions. 03:01:37

Let's go to the second stop on this road trip, the roadmap, the device itself. It's called the G2 and it's pretty easy to figure out that's because it's Bard's second generation retrievable filter, the G2. 03:01:58

What is it designed to treat? I think most of us are familiar with these conditions but just to be certain, deep vein thrombosis, that's where clots develop in the legs. You often hear of people complaining or suffering from that after long airplane rides, for example. 03:02:21

Deep vein thrombosis, when the clots break loose, can become a pulmonary embolism. That is when the clot travels generally to the heart, brain or lungs and it can be a fatal event. Each year, because of deep vein thrombosis, approximately two million Americans are affected. Statistics and the evidence will show up to 600,000 are hospitalized. Estimates are that 300,000 of our fellow Americans die every year from pulmonary embolism. Estimates show that almost a third of the patients who have had a pulmonary embolism like Ms. Booker did first in 2002, will have a recurrent one within ten years. 03:02:39 03:03:05

And this is a statistic that I always find startling. That DVT related pulmonary embolisms, in other words, pulmonary 03:03:26

emboli caused by the deep vein thrombosis is the leading cause of preventable death in American hospitals. This is not a cosmetic problem. This is not a superficial condition. This is a life-threatening condition that this filter is intended to be treating. 03:03:33 03:03:49

The United States Surgeon General has recognized that pulmonary embolism is a major health issue in this country and in 2008 he issued a call to arms to the medical community to mobilize, to treat this disease.

So what is the IVC filter? As Ms. Zaic told you, and showed you in her animation, it's placed into the interior vena cava and its purpose is to block clots coming from the legs to the heart and lungs. It is inserted, and I'm going to show you how that's done, what's called percutaneously. It's not an open surgical procedure but it's usually through an incision in the groin or in the jugular and it's inserted through a catheter and it's a procedure that only takes about 30 minutes to put this filter inside someone. 03:04:19 03:04:46

And the filter is intended and cleared by the FDA for the treatment of individuals who, for whatever reason, cannot be taking anticoagulants because if you have a clotting issue, anticoagulants are the first line of defense in medical treatment. But if you can't be on anticoagulants just like Ms. Booker could not when she had to have that surgical procedure for the cervical cancer, then a filter is a device 03:05:04 03:05:26

intended to prevent clots and work the same way or a similar way in that scenario. 03:05:31

And what the filter is supposed to do is just like a strainer. You might have at home in the kitchen. It's supposed to strain the blood of the clots and to break them up as they strike. 03:05:48

Now I would like to show you a little animation of a filter showing the clot. This is not the exact G2 filter but it's the same configuration, but we had this animation and it shows the same way that any filter would be breaking up clots. Like a strainer. 03:06:04

Let me tell you a little bit about the history of the G2 filter. You heard a lot about the Simon Nitinol filter developed by a well-known physician in Boston by the name of Dr. Morris Simon. It was introduced in 1990 and it was a permanent filter. 03:06:41

Once you put it into a person, it was there for a lifetime. The only way it could be removed would be with some open, extremely invasive, potentially dangerous surgery. Bard acquired the rights to the Recovery filter which was under development at the time by the NMT company and the Simon Nitinol filter in October of 2001 and then in January of 2003 Bard introduced, after it was cleared by the US FDA the Recovery filter. 03:07:05

Within two years and will you hear how Bard is -- its 03:07:27

business approach to things, constantly trying to innovate and improve its products, began work on the second generation filter called the G2. The FDA cleared the G2 filter for use as a permanent filter in 2005. And then between August of 2005 and October of 2007, in consultation with the FDA, Bard conducted the EVEREST clinical trial for the G2 filter and then in January 2008, the FDA cleared the G2 filter as a retrievable filter. 03:07:31 03:07:55

Retrievable filters were a revolutionary development as a tool for doctors to treat pulmonary emboli. Before retrievable filters, IVC optional filters had to be removed within 10 to 14 days. And if you had a patient that needed the filter for longer than 10 to 14 days, your only alternative was a permanent filter. 03:08:20

On the other hand, doctors did not want to put permanent filters in younger people the age of Ms. Booker. A doctor would have not have wanted to have done that where that filter has to stay there for a lifetime. In fact, will you hear the testimony of the physician who implanted the filter in Ms. Booker who says I wanted to implant a filter that I knew could be retrieved. He wanted a retrievable filter. 03:08:46 03:09:04

There were many sorts of patients, young oncology patients, young trauma patients for whom filters were never an option beforehand because no doctor would put a permanent filter in a 19-year-old motorcycle accident victim who's only 03:09:25

going to have a clotting risk for, let's say, two or three months while they are healing. But with the Bard Recovery filter, the first on the market, doctors could retrieve these filters after a lengthy period of time. It's called an indwell time, after it had been in the body for a long period of time. 03:09:30 03:09:49

You're going to hear doctors, experts, tell you that there are many reports in literature of the G2 filter being successfully retrieved a year, two years, five years after it's implanted. And until Bard started introducing to the market these retrievable filters, that was an option that physicians did not have to treat their patients. 03:10:09

And the G2 filter the doctor could choose. It was designed to be left in permanently if the doctor so chose or to retrieve, be retrieved.

And, again, it was a especially beneficial for patients with only temporary need for filter and it reduced the problems that might be associated with the long-term implantation of a filter, particularly in someone who no longer needed it. 03:10:29

These filters are also unique because they are made of a very unusual substance called Nitinol. It is an acronym for something called Nickel-titanium Naval Ordinance Laboratory and why is it called that sort of strange name? Because Navy scientists developed this substance or this material in 1962. What is unique about it is it has a shape memory. Once you 03:10:48 03:11:14

cast the device, go through the heat treatment to cast it in the shape you want it, you then can compress it but it remembers its original shape. And I say remember of course in quotations. But it will then, when released, spring back to its original shape. And that is why it's such a unique substance and it was designed initially by the Navy for military publics. 03:11:19 03:11:38

This is an animation that shows you how the filter is implanted and, again, it's through a catheter through the groin. The wire is brought up. The catheter is brought up, the filter is loaded, released and you see it. It springs back to its original shape the way it had been cast in. That's the shape memory. And there's a separate way it can be implanted with a similar sort of process but through the jugular vein and it just depends on the patient and their anatomy which direction the doctors like to use. 03:11:58 03:12:51

Now, when it's retrieved in what they call the percutaneous procedure, it's always done from the jugular. And here is an animation and this has -- this is the same filter but a later version with a little hook on it. That's what we have for the animation. The guidewire comes down and comes through the filter and then a separate device called the recovery cone comes. It collapses the filter and draws it into the catheter and then the catheter and the guidewire are removed. 03:13:08 03:13:55

Again, as I mentioned earlier, the G2 is the second generation Bard retrievable filter. Much of the evidence you're going to hear in this case, however, is going to concern the Recovery filter, the first generation filter. Maybe 90 percent of what I believe you just heard in opening statement by the plaintiff concerned the Recovery filter. But when the case is actually decided and goes to the jury, what you will be deciding is what is the evidence concerning a defect not in the Recovery filter but in the G2 filter. 03:14:02 03:14:21

And the G2 filter, the evidence will show, deserves to be judged on its own merits. It is a different filter. Sure there are similarities. Sure it was built off the original platform of the Recovery filter; but when Bard put the first retrievable filter out there on the market and began seeing the clinical experience, there were some reports of complications just as you'll learn there are reports of complications with every inferior vena cava filter on the market, the same complications: Migration, tilt, perforation, fracture. Those are not complications unique to Bard filters. Those are risks with all filters and risks that the medical community knows about and has known about long before the Recovery filter ever came onto the market. 03:14:44 03:15:04 03:15:25

But this -- Bard started assessing the clinical experience with the Recovery filter. It was also beginning the development of the second generation filter, the G2. And it 03:15:44

made specific changes and you're going to hear about those changes in great detail, specific changes to make this filter more fracture-resistant and more migration-resistant. And then the evidence will show that the question is, did those changes to the G2 filter succeed? And we submit to you the evidence is going to show overwhelmingly that they did. 03:15:49 03:16:11

Bard stopped selling the Recovery filter in 2005, two years before Ms. Booker ever received her filter. At that time the G2 had been on the market for almost two years and had a proven track record of low complications. And Bard designed the G2 filter to improve its migration resistance and to improve its fracture resistance and the evidence will show that it was a success. 03:16:35

This is a compilation of all the reports that Bard has received up through the end of 2016 regarding the Recovery filter applications and the G2 applications. Look how much better the fracture rate is for the G2 than it was for the recovery. Look how much better the migration rate was or is for the G2 than it was for the recovery. And also, as you will learn, the migrations with the G2 were very different than the migrations with the Recovery filter. They showed you evidence of migration deaths, some reports of those with the Recovery filter and, yes, there were some reports of those, just like there had been reports of migration deaths with virtually all the filters in the market. But what there hasn't been is a 03:17:02 03:17:32 03:17:51

report of a migration death with regard to the G2 filter. 03:17:57

When Bard redesigned the Recovery into the G2, it succeeded in preventing that filter from migrating to the heart. There were reports of that filter migrating downward or the caudal direction on occasion, but you'll also hear 03:18:17 testimony as to how caudal migration is often or most of the time not a significant clinical event. A filter can go upward to your heart and it can kill you. It goes downward a little bit and most doctors say that's not a serious problem. And the medical literature supports that. 03:18:39

What does that data show? That based on the reports of complications to Bard, 99 percent plus of G2 filters sold had no reported fractures, no reported migrations, and no reported perforations. That is the data that this case will turn on, I submit, and not the Recovery filter. 03:19:06

Now, let's look at the evidence concerning Ms. Booker. Ms. Zaic gave you a little bit of background from Ms. Booker. She graduated from high school in 1988. She worked as a paralegal and actress. She currently lives in Atlanta and works at the Home Depot. And here's that medical 03:19:30 history I talked to you about earlier. She suffered a heart attack in 2001. She suffered a second heart attack in 2002. She suffered her first pulmonary embolism at the age of 32 in the year 2002.

Five years later, in May of 2007, she was 03:20:01

hospitalized due to a second pulmonary embolism and she was diagnosed with deep vein thrombosis. She was hospitalized one month later due to cervical bleeding. She was diagnosed with cervical cancer and her doctors had to stop the anticoagulants, as I said, before undergoing a surgery procedure. And the G2 filter was placed to prevent a subsequent PE. She had had one just a month before. And her physician specifically wanted a filter that could be retrieved. 03:20:03 03:20:25

Now, you will hear that at that time, the FDA had only cleared the G2 filter for permanent use, not for retrievable use; but you will also hear FDA experts say that physicians may use devices how ever they think is appropriate for their patients. 03:20:47

And all the doctors out there knew that the G2 was under this clinical study and was capable, going to be capable and cleared eventually for retrieval. So many doctors were, quite lawfully and quite appropriately, and consist with the standard of medical care, retrieving this filter at that time. 03:21:04

Now, this is a very interesting event that you didn't hear anything about in the plaintiff's presentation. Two years after that filter was implanted, Ms. Booker was in the hospital for something unrelated and the fracture was observed on a film. This is a film taken in March of 2009. You can see the fractured arm adjacent to the filter and that arm is not in her ventricle. It is not in her heart. It is right next to the 03:21:25 03:22:00

filter. Right there. 03:22:04

Unfortunately, what happened was that the radiologist, Dr. Amer, wrote in his report, all he said was IVC filter is noted. Even though that arm to a layperson, lay people like us, is so apparent as being fractured right there, 03:22:22 this trained radiologist did not tell -- say anything to Ms. Booker's treating physicians, the doctors who had ordered the scan. He didn't tell them, "Oops, you better look at this filter. There's been a fractured arm." He didn't tell them, "You might want to consider retrieving it." That was, 03:22:42 unfortunately, a missed opportunity that could have prevented everything that subsequently happened to Ms. Booker, because if the doctors had noted that fracture at that point, the experts will tell you that, including the plaintiff's own experts, that filter could have been retrieved in one of these very quick and 03:23:02 easy percutaneous procedures and that strut that later went up to her heart could have been retrieved at that time. Not only is the strut obvious but look how it compares to the normal posture of the filter. Something has happened to her filter and you are going to hear testimony from experts that say that 03:23:28 whatever happened to Ms. Booker's filter is highly unusual as far as what could be the cause of it.

But look at the normal configurations of a filter in the body and how compressed hers is and turned like that. Something happened there. But regardless of what happened, 03:23:46

that is what the doctor saw in 2009 and all he reported to the doctors treating her was, "IVC filter noted." It was a missed opportunity. 03:23:49

Five years later, coincidentally in an incidental finding, the fractured filter in the heart was finally identified. But Ms. Booker cannot associate any symptoms with that filter. None of her physicians concluded that the filter strut ever caused her pain and the incidental finding in -- the finding in June 2014 was incidental when they were actually testing her for kidney stones. 03:24:08 03:24:33

And what happened then? Dr. Kang removed the filter percutaneously. You saw their animation of that. He went through the jugular vein and was able to remove that filter and one of the struts there. The other strut is completely encased in the tissue, or what's called endothelialized, and is not at risk, you will hear, for further movement. 03:24:53

He also tried percutaneously just through the catheter to pull the strut out of the ventricle. Unfortunately during that procedure he damaged her tricuspid valve. Her tricuspid valve was not damaged by the strut of the filter. It was damaged by Dr. Kang in attempting to remove that strut. Thereafter, she had to have heart surgery to repair the tear to her tricuspid valve and also to remove the strut that Dr. Kang was unable to remove. 03:25:15

Two months later she hired a lawyer and that will 03:25:43

become important later in this case, we submit to you, as you see how -- listen to the doctors talk about their conversations with her lawyers. 03:25:45

Now, the final stop in this road trip and on the roadmap is the plaintiff's burden. At the conclusion of the case, Judge Campbell will instruct you concerning the law and the plaintiff's claims and this is just an outline of what those claims are: They allege that the G2 filter has a design defect. They allege that it has a warning defect, that we failed to warn doctors of the risks. They have to prove causation. They have to prove that one of those defects, either a design defect or a warning defect, was the cause of the injuries. And then you will have to assess what role Dr. Amer, the radiologist that noted the filter, but didn't tell anyone else about its status, what role he played and what contribution that made to her injuries. 03:26:02 03:26:22 03:26:47

And throughout this all, throughout these claims, the plaintiff will bear the burden of proof by a preponderance of the evidence and you will have to determine, as I indicated earlier, whether by a preponderance of the evidence the risks of this device outweighed its life-saving benefits as the plaintiffs have argued or will argue. 03:27:13

What are the benefits? I told you about the benefits of this filter in Ms. Booker. Let's talk about the benefits of these filters generally. 03:27:31

Estimates suggest there's a 30 percent death rate with a recurrent PE. A patient who, like Ms. Booker, has had one pulmonary embolism and then has another. Anticoagulants, which are the preferred method for treating these, are not foolproof themselves. A number of people die from anticoagulants often from bleeding incidents from bleeding too much from the anticoagulants. 03:27:35 03:27:50

The statistics that Bard has compiled based on reports to us, to the company, of complications over time show that a minuscule, unfortunate but minuscule percentage of patients who receive a Bard filter are then diagnosed with a subsequent pulmonary embolism. And an even smaller percentage of Bard -- of patients receiving Bard filters suffer a fatal pulmonary embolism. 03:28:11

What do these statistics mean? I submit to you and I believe that the experts will tell you during the course of this trial that this means and shows that filters can save lives. That is their benefit. And this data shows that Bard filters are 99.99 percent effective in preventing subsequent pulmonary emboli. And this isn't just Bard and this just isn't marketing hype. This is the testimony you will hear from the plaintiff's experts and the plaintiff's treating physicians, all who agree that IVC filters just like the G2 filter save lives. 03:28:36 03:29:03

This explains why doctors use these devices, because 03:29:28

they can be life-saving and should be life-saving even though they all come with certain risks, all of them. 03:29:31

Why, you may ask, are there risks? Why can't you design a risk-free, complication-free filter? It's because the inferior vena cava is a dynamic area part of the anatomy. It is not static and still. It moves. There's blood flow, there's pressures. There's movement, there's coughing. There's compression. There are many different things that affect the shape, size on a daily basis of the inferior vena cava. 03:29:52 03:30:15

The plaintiffs have suggested that Bard never understood that environment. The evidence is going to show you, ladies and gentlemen, that the men and women, the engineers at Bard, are proven pioneers in understanding and gaining knowledge about a part of the human anatomy that 15 to 20 years ago was not that well understood, that they have been at the forefront of working with doctors and medical specialists to develop the scientific understanding of that part of the body. 03:30:32

These unusual pressures and conditions in the inferior vena cava make it very difficult and a challenge for design engineers who have to look at a lot of balancing because if you want to make a filter able to retrieve, you still have to have the anchors strong enough so that the filter won't migrate or tilt frequently. 03:30:55 03:31:17

If you want to make the filter where it can be retrieved, which physicians want these filters to be retrieved for the most part in 2018 America and even earlier back in 2007 as Ms. Booker's doctor wanted, he wanted that filter to be able to be retrieved, you can't have the arms and legs too thin. If they are too thin, they will fracture. If they are too thick and rigid, you can't retrieve it. And the same thing with the arms and leg spans. They are design balances that have to be made and the Bard engineers have worked for years and have constantly worked to understand the best way to balance and the G2 was their second effort in that regard and a success according to the data. 03:31:22 03:31:42 03:32:05

Now, as I said, these risks are well-known in the medical literature. They have been reported by the Society of Interventional Radiologists. There are thousands of medical articles reporting on complications with inferior vena cava filters and very few -- well, some of those involve Bard filters but many, many more involve other manufacturers' filters. 03:32:26

The medical community knows that, unfortunately, these complications with IVC filters are going to result in death in a small number of people themselves. 03:32:43

And the medical community understands that these filters, a certain number of them are going to penetrate, are going to migrate, are going to fracture, that there are going 03:33:03

to be other complications. This particular publication which 03:33:09
will you hear about comes from 2001, four years before the G2
filter was on the market, two years before the Recovery filter
was on the market. These complications, unfortunately, occur
with all such devices. 03:33:24

Now, Bard doesn't produce and go out and sell these
filters in a vacuum. This is a highly regulated industry and
you're going to hear about the FDA's involvement in reviewing
the G2 filter and you're going to see that the evidence shows
that it's much more than the rubber stamp that the plaintiffs 03:33:50
attempt to characterize. The FDA, as early as 1999, published
a guidance for companies seeking to develop an inferior vena
cava filter. This guidance from the FDA provides for testing.
It suggests that these manufacturers such as Bard do testing
for simulated deployment, clot trapping ability, filter 03:34:20
fracture, caval perforation, filter migration and more. And
Bard did that testing with the G2 and you're going to hear
about it in detail.

And that testing showed that Bard had substantially
improved its retrievable filter over the Recovery filter in 03:34:40
doing this testing.

This is a chart that shows a comparison of the
fracture resistance between the G2, which is on the right, and
in the earlier days of the G2, they called it different things
when it was a prototype. At this time they were calling it 03:35:00

modified RF, Recovery filter. Look how much better the fracture resistance is for the G2 filter than it was for the Recovery filter. 03:35:03

Similarly, the testing showed the same thing when it comes to migration. The migration percentage is much less in the testing, the ability to avoid migration is much greater for G2 than it ever was for the Recovery filter but there's more. The guidance and what Bard did pursuant to the guidance, and even going beyond what the FDA guidance required, included many, many different types of studies. Bard worked hand in hand with the FDA. You'll see the submissions Bard made to the agency. Pages and pages of test summaries and data and the FDA didn't just say, "Okay, fine. Go sell it." The FDA came back with questions, many questions, requiring additional data. 03:35:17 03:35:41

And only after Bard answered all of their questions did the FDA eventually clear the device and it cleared the G2 three times effectively essentially. First in August of 2005, as I indicated, for permanent use. Several months later it approved a jugular delivery system for the G2 filter, and then for retrievable use in January of 2008. 03:36:08 03:36:32

Bard's collaboration with the FDA did not end there. Bard conducted what was called the EVEREST study. The study protocol had to be reviewed and approved by the FDA. Bard provided updates to the FDA on the progress of the study. Bard provided the FDA, and you will see it, with data about every 03:36:56

adverse event that occurred in the study. And only after the completion of that study and only after reviewing all of that data, including the data of the adverse events that occurred, did the FDA clear the device for retrievable use. 03:37:00

The plaintiffs will present you a great deal of evidence concerning the Simon Nitinol filter and suggest that it has a better track record and might be a safer alternative design. But that comparison is based on flawed data because as you will hear, it is hard for physicians to monitor permanent filters the same way they do retrievable filters because doctors usually go back and see or often go back and see the condition of retrievable filters where once a permanent filter is placed, often in an elderly person, they may never be seen again, the filter itself. 03:37:25 03:37:43

This is really an apples to oranges comparison. A doctor like the doctor who implanted the filter in Ms. Booker, who wanted a retrievable filter for a woman who was in her thirties at the time would never have implanted the Simon Nitinol filter ever or any other permanent filter. 03:38:00

What's the clearest evidence that doctors don't want to use these filters? It's the sales data. This shows the sale of Bard, the G2 filter, versus the Simon Nitinol filter over the years. 03:38:22

Very few doctors are buying the permanent filter from Bard once the retrievable filter is available. The plaintiff's 03:38:42

opening focuses mostly on the Recovery filter. You will hear during the course of this trial well-paid experts that they will bring, experts that rely on just a few documents, and you'll also hear that Bard has produced in this litigation hundreds of thousands of pages of documents and you will see only a few of those from the plaintiff, often out of context. There are hundreds of medical articles out there in the medical literature. You will hear from the plaintiffs only citation to a few of those and not the whole story and we believe that the whole story will contradict a lot of what the evidence you're going to hear in the plaintiff's claim. And most of all, we believe that the plaintiff's claim is contradicted by those numbers. 03:38:56 03:39:16 03:39:39

Now, Bard's calculations of the reported complication rates are not in a vacuum. You're going to hear testimony during this trial that only recently there was a medical article published that looked at studies of retrievable filters over a 32-year period, all published studies. They tried to figure out -- it's a called a meta analysis where you look at a bunch of studies together and it showed that the rate of fracture of Ms. Booker's primary complaint about her filter with the G2 was .2 percent, much better than the Recovery filter and almost identical to what Bard's internal data shows. 03:40:01 03:40:34

Let's talk quickly about the other claim, the warning defect. As I indicated to you earlier, the medical community 03:41:02

is well aware of these risks associated with inferior vena cava filters. But in every filter that is provided, in the box is what's called instructions for use. It's a document required by the FDA. The draft of it is submitted to the FDA when Bard seeks clearance and in this IFU are warnings, a specific warning about filter fracture. And you'll see the IFU. It will be introduced as an exhibit. It's a known complication of vena cava filters. Movement or migration of the filter, perforation or other acute or chronic damage of the IVC wall. 03:41:05 03:41:23

Every doctor receiving one of these filters is warned of -- you'll hear they all know about these risks from the medical literature. They are still warned that this can occur. And Bard reminds doctors that all of these complications have been associated with serious adverse events such as medical intervention and/or death and they encourage doctors to do what the doctor did in this case, make a risk-benefit analysis of any of these complications should be weighed against the inherent risk-benefit ratio for a patient who is at risk of pulmonary embolism without intervention, and that's exactly what Ms. Booker's doctor did. Knowing the risks associated with IVC filters, he decided that the threat of a third pulmonary embolism outweighed those risks. 03:41:57 03:42:16 03:42:41

So how did the plaintiff say we didn't warn? They said we should have gone to the MAUDE database. That's the FDA's database of all records of complications with devices and 03:43:03

we should have compared our rate of complications based on that data to other plaintiff's rate of complications. They suggest we should have -- we had do exactly what the evidence will show the FDA says should not be done and that is to compare data using the MAUDE database. 03:43:07 03:43:27

There will be issues of causation for you to consider. Did the filter cause the heart surgery? There will be some testimony that that piece that was in her heart. If her tricuspid valve had not been damaged, could have been left there. Many doctors would have left it there. It was not producing symptoms. It was encased. It was not in danger of moving and as strange as it is for us as those of us who are lay people to understand, and I was kind of surprised by this when I first heard it, doctors don't consider it a serious issue if people are carrying around metal bits sometimes in their body. Most people who have pacemakers have little metal parts of the lead that are sometimes retained in the body. You will hear testimony that this could have been left. You will hear testimony, too, as I indicated earlier, that the doctors had more than five years to discover the fractured strut next to the IVC filter when it could have been removed percutaneously. 03:43:52 03:44:14 03:44:37

You will hear that it was Dr. Kang's attempt to remove strut and not the strut itself that damaged her tricuspid valve. And you will hear no evidence that the 03:45:04

warning was somehow a cause of this incident. Dr. D'Ayala testified -- never said in his deposition -- actually said he read the IFU. He said it was available to him, the instructions for use. But just because something is available to you doesn't mean you've read it. And he didn't seem to recall it and there will be a serious question as to whatever we had put in that IFU could have caused this injury if he did not rely upon it. 03:45:06 03:45:24

And then we will also have an issue for you to consider concerning Dr. Amer's fault. That's again what I mentioned. What should he have said? What should he have done in 2009 when he saw that strut presumably? It's so obvious but said nothing to the doctors that were treating her. And then she will have to meet her burden of proof of showing what her damages are. 03:45:42 03:46:05

Ladies and gentlemen, as I said earlier, I hope you will keep an open mind until you have heard the whole story. And I believe that when you have heard the whole story, the evidence is going to show you that these filters certainly have risks but with the G2 filter, those were very low risks, as the data shows, and these filters have very huge benefits. They can save your life just like they most likely saved Ms. Booker's life. The evidence will demonstrate that low risk. 03:46:30

And, ladies and gentlemen, at the conclusion of the 03:46:57

case, I submit to you that all of the evidence taken together, the whole story, will show you that Bard in this case has been wrongly accused. And at that time, I will ask you, as members of a responsible jury, to please return a verdict in favor of my clients, Bard and Bard Peripheral Vascular. 03:46:58 03:47:13

Thank you very much for your attention.

THE COURT: All right. Thank you, Mr. North.

Ladies and gentlemen, that concludes the opening statement but we're going to keep going until 4:30 so we can make progress in getting the case to you and so the next step is going to be the plaintiff's first witness. 03:47:28

Counsel, if you want to move that lectern, you can.

Ladies and gentlemen, if you want to stand up for a couple of minutes while they get organized for the first witness, feel free to do that. 03:47:42

All right. Counsel, your first witness?

MR. O'CONNOR: Yes, Your Honor. Andrzej Chanduszko.

THE COURT: Is he here in the courtroom yet?

COURTROOM DEPUTY: Sir, if you'll please come forward and raise your right hand, please. 03:49:12

(ANDRZEJ CHANDUSZKO, a witness herein, was duly sworn or affirmed.)

COURTROOM DEPUTY: Sir, could you see please spell your last name for us?

THE WITNESS: Spell it? 03:49:26

COURTROOM DEPUTY: Yes, please. 03:49:27

THE WITNESS: C-H-A-N-D-U-S-Z-K-O.

THE COURT: There's no K?

THE WITNESS: Z-K-O.

COURTROOM DEPUTY: Thank you, sir. Please come have a seat. 03:49:41

THE COURT: Go ahead, Mr. O'Connor.

MR. O'CONNOR: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. O'CONNOR: 03:50:04

Q. Would you please state your full name?

A. My full name is Andre Chanduszko.

Q. Mr. Chanduszko, my name is Mark O'Connor. You and I have never met before; is that correct?

A. Correct. 03:50:20

Q. You understand I'm one of the lawyers that represents Sheri Booker?

A. Yes.

Q. Where do you currently work, Mr. Chanduszko?

A. I work at Bard Peripheral Vascular. 03:50:28

Q. And what is your position there?

A. My position is principal engineer.

Q. Principal engineer?

A. Yes, that's correct.

Q. And when did you first come to Bard? 03:50:39

A. In 2004.
Q. And you came from a company called Nitinol Medical Technology, NMT?
A. That's correct.
Q. And you were an engineer there; is that right? 03:50:52
A. Yes.
Q. And when you were at NMT, you were involved in the recovery project, the Recovery filter project?
A. Yes, that's correct.
Q. The Recovery was developed after the Simon Nitinol filter; 03:51:04
correct?
A. That is correct, yes.
Q. And Bard had purchased the Recovery and the Simon Nitinol filter. Is that fair?
A. Could you repeat that, please, sir. 03:51:19
Q. Sure. Eventually, the Simon Nitinol filter and the Recovery filter became products of Bard; true?
A. Yes, that's correct. That's true.
Q. And when you went over to Bard, you became involved in 2004 in the Recovery G1A project. Is that fair? 03:51:35
A. Yes, that's fair.
Q. And the Recovery G1A is the G2?
A. Yes.
Q. Second generation of the Recovery filter?
A. That is correct. 03:51:49

Q. Thank you. Now, initially, you were a project leader of the G2 project when you arrived at Bard in August of 2004; is that correct? 03:51:50

A. Yes, I was.

Q. And eventually you were replaced? 03:52:09

A. Yes. So the -- when I came, the team was in the process of being hired so then once the team was complete, I focused more on the technical side and there was another person who became the project leader.

Q. The G1A project was an effort to redesign the Recovery filter. Fair? 03:52:32

A. That's one way to describe it.

Q. And when you were involved in the G2 project, the goal was to make the G2 more migration-resistant -- resistant to migration compared to the Recovery filter; true? 03:52:58

A. That was one of the goals, yes.

Q. And another goal was to redesign the G2 so that it would be more resistant to fracture compared to the Recovery. Is that correct?

A. So, yes, to design the G2 so it would be more fracture-resistant to the Recovery filter. 03:53:16

Q. There were two goals for the G2: To make it more resistant to migration and make it more resistant to fracture compared to the earlier, the predicate device, the Recovery filter. Fair? 03:53:36

A. Those were the main two goals, yes. 03:53:38
Q. Now, you are an engineer; correct?
A. Yes, I am.
Q. And you have attended engineering school?
A. Yes. 03:53:49
Q. You are not licensed in any state, are you?
A. No, I'm not.
Q. Since you got out of school, you have been working for medical device companies; is that correct?
A. Yes. 03:53:59
Q. You do agree, Mr. Chanduszko, that there are safety responsibilities that a device manufacturer has?
A. Yes, absolutely.
Q. For one, the manufacturer must make a device that is as safe and effective as possible; true? 03:54:19
A. So I don't know. That sounds to me like legal term maybe. I think we all strive to design a device that is as safe as possible but I don't know if I can answer that in a legal capacity.
Q. Well, based upon your engineering background and what you've testified to before, do you agree with the basic concept that a manufacturer must make a device as safe and as effective as possible? Does that make sense to you? 03:54:47
A. Generally speaking, as an engineer, yes.
Q. A medical device manager should never put profits over 03:55:10

patient safety; correct? 03:55:14
A. Yes. In my opinion, yes.
Q. Patient safety should be a priority for companies like Bard; true?
A. Yes, absolutely. 03:55:21
Q. So if Bard is bringing a product or a device to the market, it must take steps that it is putting patient safety number one when it brings that product. Do you agree with that?
A. That would be my opinion, yes. 03:55:37
Q. And for medical devices that go in the human body, you agree, don't you, Mr. Chanduszko, that a manufacturer like Bard must conduct the necessary research and testing to understand the anatomical environment where the device will be placed?
A. Yes, generally speaking, yes. 03:56:08
Q. Essentially, the manufacturer, before it places a device like an IVC filter on the market, must have an understanding of the anatomy where that device is going to be?
A. Yes, as much as possible.
Q. Well, you agree with that, don't you? 03:56:27
A. Yes.
Q. Now, you told us that design goals of the G2 were to be more resistant to migration and more resistant to fracture compared to the Recovery; correct?
A. Yes, that is correct. 03:56:54

Q. But the design goals of -- involved in the G2 did not include improvement of tilt resistance compared to the Recovery; fair? 03:56:59

A. I'm not sure if that's a true statement.

Q. All right. Let me get your deposition. 03:57:20

MR. O'CONNOR: May I approach the witness, Your Honor?

THE COURT: Is that with a copy of the deposition?

MR. O'CONNOR: This is a copy of his deposition that was taken on October 10, 2013. 03:57:47

THE COURT: Why don't you bring it to Traci if you would and she'll put it in front of the witness.

BY MR. O'CONNOR:

Q. All right. Mr. Chanduszko, do you recall going -- being deposed on October 10, 2013, in a case against Bard, the company you work for? 03:58:34

A. Yes, I do.

Q. And you've reviewed that deposition, have you?

A. I have.

Q. And if you would, would you please go to page 36 and go to line ten and the question to you was: You didn't answer my question. Was one of the project goals for redesigning the Recovery filter into the G2 filter to improve its performance in respect to tilting? 03:58:47

And your answer was: Generally speaking, No. 03:59:16

Now, did I read that correct? 03:59:20

A. I'm sorry. Could you repeat the page number?

Q. Oh. I'm sorry. Go to page 36. I thought you were there.

A. Yes, I am now.

Q. And I am beginning to read on page 36 at line 10. Are you there? 03:59:30

A. Yes.

Q. All right. Let me just make sure that I am reading this correctly, okay?

The question began: You didn't answer my question. 03:59:41
Was one of the project goals for redesigning the Recovery filter into the G2 filter to improve its performance in respect to tilting?

Now, did I read that question correctly?

A. Yes. 03:59:58

Q. And would you please read to the jury your answer at line 14?

A. Generally speaking, no.

Q. Thank you.

And also one of the design goals of designing the 04:00:18
Recovery into the G2 did not include resistance to perforation; is that correct that?

A. Wouldn't be completely my understanding, no.

Q. So you're saying I was not correct with that statement?

A. So -- 04:00:41

Q. Let's go to your deposition. 04:00:43
A. So there are --
Q. Hold on. We'll go to your deposition. Go to page 38. At line one. Let me know when you're there.
A. Yes, I'm there. 04:00:56
Q. The question beginning at page 38, line one -- and, again, we're looking at your deposition dated October 10, 2013; correct?
A. Yes, that's correct.
Q. The question was: Mr. Chanduszko, was one of the project goals in redesigning the Recovery filter into the G2 filter to improve its performance in respect to perforation? 04:01:14

Now, did I read that question correctly, sir?

A. Yes.
Q. And your answer was again: Generally speaking, no. 04:01:29

Did I read that correctly?

A. That's part of the answer.
Q. Yes. And you go on to say: The project goals were stated, it is my best recollection, as to improve migration resistance and improve fracture resistance. Those were the two goals. 04:01:45

True?

A. That was my answer, yes.

MR. CONDO: Your Honor, can we have the following question and answer read, please. 04:01:55

THE COURT: You can do that on cross-examination. 04:01:57

MR. CONDO: Thank you.

BY MR. O'CONNOR:

Q. Mr. Chanduszko, let me talk to you about a different area. I'm done with that. Thank you -- 04:02:18

A. You're welcome.

Q. -- for looking at that for me.

I want to talk to you about the concept of worst case condition, okay?

A. Sure. 04:02:31

Q. To be safe and effective, a manufacturer like Bard must understand the worst case conditions where a device -- that a device will be exposed to. Do you agree with that?

A. So as reasonably expected, yes. I don't know if it's possible to know every worst case condition but these certainly 04:02:49 need to be researched.

Q. Do you agree, Mr. Chanduszko, that in designing and developing a device, that a manufacturer must understand the worst case scenarios, yes or no, please.

A. To the extent possible, yes. 04:03:09

Q. And to be safe and effective, a manufacturer like Bard should test the device under reasonably foreseeable worst case conditions. Do you agree with that?

A. Yes.

Q. Knowing, understanding and testing for the worst case 04:03:38

scenario protects patient safety; true? 04:03:41
A. It might, yes.
Q. Isn't that the goal? To know the worst case conditions, test for it, research it and the goal there is to put the patient safety as a priority? 04:03:58
A. So the patient safety is a priority and, yes, the research needs to be done to look at the worst case scenario.
Q. I think we can just agree that one reason that engineers like you who work for companies like Bard study research and test for reasonable foreseeable worst case conditions among 04:04:23
others is for patient safety. Do you agree with that concept, sir?
A. Yes.
Q. Now, in terms of understanding the vena cava, that is the part of the anatomy that is affected by an IVC filter; true? 04:04:51
A. I'm sorry. You said is affected by IVC filter.
Q. Let me try again. IVC filters are designed and developed to be placed in the vena cava; correct?
A. Yes, that is correct.
Q. And the vena cava is the largest vein in the human body; 04:05:13
true?
A. It is true.
Q. And you agree that Bard should understand the anatomy of the vena cava to understand what type of conditions a filter, an IVC filter, will be exposed to after it's implanted? Do you 04:05:31

agree with that concept? 04:05:37
A. Yes. Generally speaking, yes.
Q. So, for example, one thing Bard should have been aware of before ever putting the Recovery or the G2 on the market was distention and how that worked on the vena cava. Do you agree 04:05:54
with that?
A. Yes.
Q. How the vena cava would expand, how it would contract. That's something that Bard was required to know before it put an IVC filter on the market. Do you agree with that? 04:06:12
A. So I don't know if that's a legal question.
Q. Sir, can you answer the question yes or no?
A. So I'm not sure.
MR. CONDO: Your Honor, can he be permitted to finish his answer? 04:06:25
THE COURT: Let's say this: Sir, if he asks you to answer yes or no, try to do that. If you can't, you can tell him, "I can't answer that question yes or no," and he can put a different question to you.
Go ahead. Reask the question if you would, Mr. 04:06:37
O'Connor.
MR. O'CONNOR: Sure.
BY MR. O'CONNOR:
Q. Do you agree that before putting the filter on the market, Bard was required to research and have an understanding as to 04:06:51

how the vena cava expanded and contracted? Do you agree with that concept? 04:06:59

A. Yes.

Q. Thank you. And when you came to Bard and when you were deposed, you did not know what, if anything, Bard knew about distention of the vena cava; is that correct? 04:07:15

A. So when I came to Bard, it was 2004 and when I was deposed, was much later so I'm not sure if I understand the question. Maybe you can rephrase.

Q. Well, let's just make sure we understand a couple of concepts. Distention means what as it relates to the vena cava? That's a term you're familiar with; true? 04:07:41

A. Yes. So distention means that it's an expansion of the diameter.

Q. And that is an important concept to know when you are going to design a filter that is represented will stay in place and stay centered in the vena cava; correct? 04:07:54

A. So I agree to at least parts of what you said, yes, it is an important concept to understand when you design a filter.

Q. And as I understand what you have gone and testified about, Mr. Chanduszko, you don't know what Bard did, if anything, that the company did to understand the concept of distention. Is that fair? 04:08:40

A. Yes, that's fair. I was not with Bard at the time.

Q. And you don't know what Bard knew or understood about 04:09:06

distention before it released the Recovery correct? 04:09:09
A. Yes, that's based on my understanding, yes, that's correct.
Q. And at the same time, you do not know what, if anything, Bard knew about distention of the vena cava before it released 04:09:26
the G2 filter; true?
A. I know there was some work done because the filter was redesigned to accommodate that. So, yes, there was knowledge about it.
Q. Well, let's go to your deposition at 134. 04:09:49
MR. CONDO: Same deposition?
MR. O'CONNOR: Yes, sir.
BY MR. O'CONNOR:
Q. So if you begin at line ten, the question was: And with respect to the G2, you acknowledge that you don't know what 04:10:24
Bard actually did to determine how far the vena cava could distend?
And your answer was: I don't recall anything specific.
Now, did I read that correctly? 04:10:36
A. Yes.
Q. Now, while you were at Bard and you were involved in the G2, you did become involved in some testing; correct?
A. Yes, that is correct.
Q. And is it fair that you used a computer analysis known as 04:11:27

the Finite Element Analysis? 04:11:33
A. So I didn't use it myself but we hired other people to run these tests.
Q. Now, you became aware, didn't you, that the G2 was having issues with fracture among others; correct? 04:11:49
A. At what time point?
Q. Well, during the period you were at Bard after the G2 was released you became aware that the G2 was migrating, tilting, perforating and fracturing; correct?
A. Yes, there were some reports that reported these kind of accidents, yes. 04:12:09
Q. And you received those reports; correct?
A. So I wouldn't receive them personally but we had -- we would look at these reports during team meetings.
Q. And you came to learn that the G2 filter could migrate caudally; true? 04:12:26
A. Yes, that's correct.
Q. Migrate downwards; right?
A. Yes.
Q. You came to learn that the G2 filter could tilt off center into the vena cava; true? 04:12:36
A. Yes. It would tilt occasionally.
Q. And you learned that not only could it tilt but it could also perforate through the wall of the vena cava; right?
A. So perforate or penetrate, yes, it's -- 04:12:56

Q. That's something you learned, you came to know? 04:12:59
A. Yes.
Q. And you also learned that in addition to tilting and perforating, that the legs, the arms on the G2 filter, could fracture; true? 04:13:12
A. Yes, low rates but yes.
Q. And a finite and element analysis is a way that engineers go about resolving engineering problems; true?
A. That's one of the tools, yes.
Q. And, sir, the FEA was the only test done at Bard, the only 04:13:32 test done to investigate the likelihood of fracture in the G2 filter. Do you agree with that?
A. That's not my understanding, no.
Q. All right. Then let's look at another deposition.
MR. CONDO: Could I have the date, please, Mark? 04:14:09
MR. O'CONNOR: Yes. It is going to be June 21 of 2013.
BY MR. O'CONNOR:
Q. All right. Mr. Chanduszko, do you recall having your deposition taken on June 21, 2013? 04:15:03
A. Yes, I do.
Q. And I perhaps should have explained this before but can you and I agree that a deposition is a procedure where you are asked questions by a lawyer. There's a court reporter that puts you under oath and you're sworn to tell the truth just 04:15:21

like you are here in this court. Is that fair? 04:15:24
A. Yes, that's a proper description.
Q. And at your depositions, you were represented by the attorneys representing Bard, your company; correct?
A. Yes. 04:15:35
Q. And you look like you were at that deposition that day for a long time in New York City; is that right?
A. Yes.
Q. All right. So, Mr. Chanduszko, if you can go to page 237 of this deposition, sir, and let me know when you're there. 04:16:12
A. Yes, I'm there.
Q. All right. Thank you.
At that time, the attorney that was representing the plaintiff in that case was asking you questions in New York City; right? 04:16:38
A. Yes.
Q. And at line ten he asked you a question: Please describe all stress analysis that was carried out to investigate the likelihood of fatigue failure and/or fracture of the G2 IVC filter. 04:16:55
Did I read that question correctly?
A. Yes.
Q. And you responded with a clarification. You said: At the time of development?
And his answer was. Yes. 04:17:05

A. Yes. 04:17:08
Q. You understood that this attorney's question was directed to your role at the time that the G2 filter was being developed; right?
A. Yes. 04:17:18
Q. And he asked you about the tests that were carried out to investigate the likelihood of fatigue failure and fatigue fracture and your answer was: That's the computer-aided engineering study that I mentioned.

He said: The FEA, yes. 04:17:36

He asked you then: Anything else?

And you said: Not to my recollection.

Now, did I read the questions and answers accurately today?
A. Yes. 04:17:48
Q. So at that time you were asked about what was done to investigate fatigue failure and how that would result in fatigue fracture of the G2 arms and the G2 legs and you understood that was the point of the question; true?
A. As I understood, he asked me specifically about analysis as opposed to everything that was done. 04:18:08
Q. All right. And what your answer was is that you did do the FEA; correct?
A. As far as the analysis, yes.
Q. All right. Thank you. 04:18:21

Now, one thing that you knew back before the G2 was ever released was you knew about the concept of electropolishing; correct? 04:18:22

A. As a concept, yes.

Q. And you knew as an engineer, a Bard engineer who became aware that Bard filters were fracturing, you were aware that there were ways to use electropolishing to make a filter more resistant to fracture, didn't you? 04:18:40

A. So that's a very general statement and it may or may not be true. 04:19:03

Q. Well, do you agree electropolishing can help with fracture resistance, yes or no?

A. I'm afraid I can't answer it yes or no. I know it can help and I also know it can hurt.

Q. Let's go to your June 21 deposition at 241. 04:19:31

THE COURT: Is that the same one you just had him look at?

MR. O'CONNOR: Yes, Your Honor.

BY MR. O'CONNOR:

Q. June 21, not the October. The New York deposition. The one we just talked about. 04:19:38

A. Yes.

Q. And if you go down to 241 at line 19, the New York attorney asked you: Would you agree that electropolishing is good because it helps with fracture resistance? 04:20:20

And your answer was: It helps, yes. 04:20:23

Now, did I read the question and answer accurately?

A. So the way I heard is actually incorrect.

Q. Did I read it incorrectly?

A. I believe so. 04:20:35

Q. Let me try it again. The question was: Would you agree that electropolishing is good because it helps with fracture resistance?

Now, did I read that question correctly?

A. Yes. 04:20:44

Q. And your answer was: If it helps?

And your answer was: Yes.

A. That's correct.

Q. Okay. So now we have read your -- the question and answer accurately; right? 04:20:55

A. Yes.

Q. And just so you and I can leave this point, back before the G2 was released, you, as an engineer, were aware of methods and things that could be done with help like making a device like a filter resistant to fracture; true? 04:21:22

A. If I knew of the things that could make it more fracture-resistant.

Q. Like electropolishing; correct?

A. So, again, I can't say that I knew that electropolishing would help G2 filter as it was being developed. I cannot say I 04:21:36

knew that. 04:21:41
Q. But you knew that that was something that could be considered to help with fracture resistance back at that time. Fair?
A. Just as a general consideration among other things, yes. 04:21:50
Q. Thank you.
Well, you were aware of electropolishing when you did the research for the development of the G2; true?
A. I just know about electropolishing, yes.
Q. And you testified that electropolishing can help with 04:22:18
respect to both corrosion and making something more resistant to fracture. You agree?
A. It can but it also can hurt these things.
Q. Well, let's go to page 245, just so you can see where I got your testimony from and how you answered it then; okay? 04:22:38
And same deposition again, the June 21 New York deposition.
All right. And the question and answer goes to 247, Mr. Chanduszko, but you were asked about a document and I can show it to you when we have probably more time, where somebody was talking and made a representation about electropolishing 04:23:35
and the point is you knew about electropolishing as a concept when the G2 filter was being developed; true?
A. Just electropolishing as a concept, yes, I knew that.
Q. Now, just I think we're getting --
MR. O'CONNOR: Your Honor, I probably am going to go 04:24:22

into another area that is going to take some time. Would this be a good time to -- 04:24:24

THE COURT: Not yet. Let's go for five more minutes, right to 4:30.

MR. O'CONNOR: All right. Thank you. 04:24:35

BY MR. O'CONNOR:

Q. All right. Mr. Chanduszko, you were charged to design out the risk of the failure modes in the G2 filter. Was that one of your responsibilities?

A. I'm sorry. I did not understand that question. 04:24:59

Q. In the G2 project, among your responsibilities was to design out the risk of complications in the G2; correct?

A. No. That's -- I don't think that's correct.

Q. Well, let's go to your deposition again on June 21 at 267 and I'm looking at 267, line 25, on to 268 on the New York deposition. Tell me when you're there. June 21. 04:25:44

A. Yes, I'm there.

Q. All right. So the question was: Were you asked to work on a design or to develop a design for the G2 that would design out that risk? 04:26:00

Do you see where I read?

A. Yes.

Q. And your answer was: I was asked to minimize any risk possible.

Did I read your answer correctly? 04:26:11

A. That is a correct answer. 04:26:13
Q. And is it fair to say, Mr. Chanduszko, before we wrap it up today -- we'll continue tomorrow -- that you agree after the Bard was designed researched and released to market that the G2 was still experiencing tilting? 04:26:36
A. After the filter was designed and released?
Q. Yes.
A. Yes.
Q. And the filter was experiencing migration?
A. Yes, that's correct. 04:26:50
Q. And that the filter was experiencing fractures?
A. True.
Q. And you were aware of that?
A. Yes.
Q. And you were aware that doctors and patients were reporting to Bard that the G2 was fracturing, that the G2 was migrating, and that the G2 was tilting? 04:27:02
A. Yes.
Q. And you knew that early into the release; true?
A. I'm sorry. Could you rephrase it, please. 04:27:18
Q. Sure. You became aware of that after the Bard filter was released into the market; correct?
A. Yes. After it was on the market for whatever long time I did get reports, yes.
Q. You knew and Bard was aware that the G2 had issues 04:27:45

migrating downward caudally; correct? 04:27:48
A. Yes.
Q. And you agree that the design of the G2, the design that you were involved in, predisposes the filter to caudal migration? 04:28:04
A. I'm not sure if I agree with that statement.
Q. Well, did you testify to that in October of 2010?
A. I'm not sure.
Q. Well, let's find out.
I'm looking at your October 2010 deposition, sir. 04:28:29
MR. CONDO: '10 or '13?
MR. O'CONNOR: I'm sorry. October 10 of 2013, yes.
MR. CONDO: Thank you.
BY MR. O'CONNOR:
Q. So the question to you was at line 16. Can you go there, page 275, line 16? 04:29:04
A. I'm sorry. I don't know if I have the correct one.
Q. The October 10. You have two depositions.
A. I have June.
THE COURT: Do you have the October one? 04:29:19
COURTROOM DEPUTY: I do.
BY MR. O'CONNOR:
Q. So I'm looking at page 275, Mr. Chanduszko, and, again, we're talking about your October 10, 2013 deposition. Let me know when you get there and I'm looking to start the question 04:29:45

at line 16. 04:29:48

A. 275 and line 16?

Q. Yes, sir. And let's look at it together. The question was: So what would predispose the G2 filter to caudal migration over the Recovery filter? 04:30:17

Do you see where I'm reading from?

A. Yes, I do.

Q. And your answer was: I think the hypothesis is that since the -- Recovery filter arms, they engage in the cava wall, which, you know, occasionally causes the saluting arm, the G2, 04:30:29 they don't engage as readily, and therefore, they'd be less resistant to caudal migration.

Now, did I answer that correctly -- I mean, did I read that correctly? Excuse me, sir.

A. Yes. 04:30:49

Q. And what you were explaining to the lawyer in New York was your theory why the G2 filter migrated downward compared to the Recovery which was known to go upward in the vena cava; correct?

A. So I'm not sure -- 04:31:04

Q. You were asked questions about caudal migration?

A. Yes, caudal which is down.

Q. And that is something that you're aware of was occurring with the G2 filter?

A. Yes. 04:31:13

Q. And you gave your theory why that was happening, that the arms of the G2 were not attaching like the arms of the Recovery to the vena cava wall; correct? That's a fair reading of that testimony? 04:31:14

A. So that was the difference -- that was the change that made the G2 filter less resistant to the caudal migration. 04:31:31

Q. And, sir, my question is just clarifying so you and I can make our point here today and so the jury can understand what your theory was is that the reason that the G2 migrated downward was because it was not fixing itself to the vena cava walls the same way the Recovery filter was; correct? 04:31:58

A. So that's not exactly correct.

Q. Hang on. Let me just --

THE COURT: Mr. O'Connor, let's address this tomorrow morning. 04:32:16

MR. O'CONNOR: All right.

THE COURT: I think this might take a few minutes and we're beyond 4:30.

MR. O'CONNOR: Thank you.

THE COURT: Ladies and gentlemen, we're going to break for the day. Let me mention two things. It's the same reminder. Please don't talk to anybody about the case or do any research. 04:32:23

Secondly, please, if you would factor in traffic and things like that in getting to the courthouse tomorrow to make 04:32:33

sure you're here a few minutes before nine so that we can start right at nine. We're going to try to really run things on time so we can get all of the evidence in the time we've told you it will take in this trial. And we will plan to see you in the morning. Thanks very much. 04:32:36 04:32:50

(Jury departs at 4:33.)

THE COURT: All right. Sir, you can step down.

THE WITNESS: Thank you.

THE COURT: Please be seated.

All right. Counsel, for your information, as of the close of today, plaintiff has used one hour and 47 minutes. Defendant has used 55 minutes. 04:33:37

We'll plan to get started at 8:30. If you'll be in here tomorrow morning, I'll come in to see if there's any issues we need to address. One thing I didn't mention earlier that I think you already understand is when we're questioning witnesses, we'll use a one-lawyer rule, meaning the lawyer who is going to do the questioning does the objecting as well. 04:34:00

Are there any other matters we need to take up before we break for the day? 04:34:14

MR. NORTH: Nothing for the defendant, Your Honor.

MR. O'CONNOR: I don't think we have anything else.

THE COURT: Okay. We'll see you at 8:30. Thanks.

(Whereupon, these proceedings recessed at 4:34 p.m.)

C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 15th day of March, 2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP